An eHealth Approach for Optimal Venous Thromboembolic Disease Management

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Abstract: This paper presents results obtained from the use of an e-Health monitoring system proposed for patients suffering from Thromboembolic Cardiovascular Diseases (CVD) such as Pulmonary Embolism (PE) and Deep Venous Thrombosis (DVT). Time is decisive in patients with these conditions and the faster the medical information gets seen by trained medical staff, the better it is for the patient's health management. Unregistered or unnoticed symptoms, as well as late reaction to them may lead to major health deterioration. The main objective of the study has been to propose and test a complex Cloud based system that could improve the well-being and health outcomes for this category of patients. Using a mobile phone application, the system is designed to acquire relevant patient health data, such as heart rate/oxygen saturation, ECG and blood pressure from different sensors, then through the internet connection the data is saved into a private cloud infrastructure from which it is accessed and displayed onto the doctor's interface. During the study 31 patients used the proposed system and improved their overall health status in comparison with the control group($p<0.5$). The proposed system has proven to be one that could improve health care services in such a way that it can decrease patient-doctor direct interaction while preserving in the same time a high-quality treatment.

Keywords: Tele-monitoring; pulmonary embolism; SOA; e-Health; cloud computing

1. INTRODUCTION

Venous thromboembolism (VTE) represents the formation of blood clots in the veins. When a clot forms in the profound venous system, usually in the leg, it is called a deep vein thrombosis or DVT. When the clot breaks loose and travels to the lungs, it is called a pulmonary embolism or PE. Together, DVT and PE are known as VTE - a dangerous and potentially deadly medical condition (World thrombosis day, 2016). Each year, approximately 10 million cases of VTE are occurring worldwide (Jha et al., 2013).

Only in Europe, there are 544,000 VTE-related deaths every year (Heit, 2005).

In addition to the disease burden that VTE produces it causes a significant global economic burden. Multiple paraclinical tests and treatments, prolonged hospitalisations and follow-up care - including recurrent VTE - are extremely costly. By optimising VTE prevention, healthcare systems can cut the costs, improve outcomes and ultimately save lives (World thrombosis day, 2016).

Telemedicine allows monitoring of vital stats and provision of health care services, using the information and communication technology, in situations where the caregivers and the patients are not in the same location.

Telemedicine and mobile health tools can enhance VTE prevention by empowering the patient towards implementing more efficiently the secondary prevention methods, closely monitoring the side effects of the anticoagulation therapy and allowing early discovery of recurrence signs.

The mentioned real time solution is comprised of a system that runs over a Service Oriented Architecture (SOA) involving three main components. The first component is represented by a smartphone application, which resides on a phone that needs to be offered to a patient enrolled in the rehabilitation programme. The patient receives also several medical devices for monitoring his health parameters.

These devices communicate with the mobile application, which in turn collects the data and sends it via the Internet through the second component, a cloud infrastructure. The cloud infrastructure maintains several machines where data is stored and from which it gets to be used by the third component. The third component is the application that the doctor uses in order to remotely monitor a patient.

This paper is structured as follows: in section 1 we introduced PE and DVT pathology and the concept of telemedicine. Section 2 discusses the existing state of the art in tele-medicine. In Section 3 we introduced PE and DVT pathology and the concept of telemedicine. Section 4 illustrates the Remote Monitoring System Architecture. Section 5 presents the clinical study design. Section 6 present the obtained results. Section 7 concludes the paper.

2. STATE OF THE ART

Conceptually telemedicine represents the use of information and telecommunication technologies to facilitate the provision of healthcare services from distance. By using it the access to medical services in distant rural communities is increased, eliminating the distance barriers and the lack of the onsite medical personnel. Telemedicine is also used in the emergency sector to provide medical data related to critical patients in different life threatening conditions.

As a product, although it has a lot of precursors the concept belongs to the 20th century telecommunication and information technologies. These technologies allow an easy interaction between patient and health personnel with both convenience and fidelity, as well as the transmission of medical, imaging data from one location to another.

The previous forms of telemedicine developed using telephone and radio have been supplemented with video telephony, advanced diagnostic methods supported by cloud based distributed client/server applications, and additionally with wireless capable medical devices to support in-home care (Sachpazidis, 2008).

By analysing the worldwide demographic trends, it appears that the increasing life expectancy will have a large influence on the future burden of disease. Globally, the increasing number of over 60 year's population leads to an increase in noncommunicable chronic disease and the comorbidities that these imply. Ehealth solutions development will produce a substantial impact on the future healthcare system and the use of the remote systems will increase in quantitative terms (Mathers et al., 2005; Siewert et al., 2010).

Another important consequence of the increased number of patients with chronic diseases and multi-morbidity followed by the subsequent higher medical treatment costs, is the need of a new patient management attitude from the current curative intentions toward more preventive and palliative goals such as improved symptom control, increased mobility and autonomy, social inclusion, competence in daily life, and maintenance of good overall quality of life.

Monitoring through telemedicine is becoming an important component of the treatment concept for many of the patients. This new approach implies the development of novel and innovative solutions that can ensure adequate medical management and a good quality of healthcare for these patient groups (Maher et al., 2009; Schulz et al., 2004).

The aging populations, accompanied by urbanization and the sparse distribution of the medical professionals with decreased coverage on rural regions tends to restrict regular visits to practices and clinics for older patients with limited mobility. In order to improve this problem many different telemedical systems have been developed and used on various scales from merely experimental to broader routine (Ekeland et al., 2010).

In (Loane et al., 2008), a technical review of multiple CVD studies carried out between 2000 and 2014, show a significant improvement on the general health conditions for patients involved in telemedicine-assisted treatments. The study reports overall improvements on health risk statistics for patients with CVD afflictions.

Advancements in EHR processing and storing are proposed in (Terkelsen et al., 2008) by using a standardised patient and hospital database, compatible with multiple health service providers.

mHealth is a component of eHealth. To date, no standardized definition of mHealth has been established. The Global Observatory for eHealth defined "mHealth or mobile health as the medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices." It involves the use and capitalization on a smartphone`s core utility of voice and short messaging service (SMS) as well as more complex functionalities and applications that include general packet radio service (GPRS), third and fourth generation mobile telecommunications (3G and 4G systems), global positioning system (GPS), and wireless and Bluetooth technology (Emerging mHealth, 2014).

Many advancements in m-Health have been developed in the medical field research area. The world is currently crossing an extraordinary phenomenon by observing the exponential growth of mobile communications not only in developed countries but also in the developing countries, were mobile technology is bypassing the classical telephony systems this way allowing people to communicate between distant geographical locations which until now were inaccessible. (International Telecommunications Union, 2010).

With the increase of mobile broadband speed through 3G innovation, it is expected that an increased number of people will have access to the Internet. Alongside benefits to increased business and information access, innovative thinkers are seizing the opportunity to harness the power of mobile technologies for the benefit of public health. The current mHealth solutions allows patients to be connected to services which include health information on demand, health record management, and the remote, real-time monitoring of chronic conditions such as diabetes mellitus, asthma, and blood pressure management (Rahman et al., 2007; Ivatury et al., 2009; Corker et al., 2010).

In (Donya, 2007) there were expressed benefits of using mobile devices for health reporting in hospital zones. These can improve existing systems by providing an intelligent decision support system for monitoring the patient's health condition and predict the clinical condition in real-time.

Mobile technologies have already started shaping and will continue to change the lives of millions of people around the world, although most particularly in high-income settings.

This change is called by a lot of analysts a revolution: almost 90% of the world's population might benefit from the opportunities mobile technologies represent, and at relatively low cost. Yet the health sector has been slow in adopting mobile technologies into routine operations, which would benefit patients and providers alike (Emerging mHealth, 2014).

Despite some challenges and failures, mHealth telemedical concepts have considerable potential to support healthcare in particular for patients with noncommunicable chronic diseases (Yang et al., 2009).

At the current moment, there is very little evidence related to the mhealths role in the monitoring and recovery process of patients that suffered a pulmonary embolism or deep venous thrombosis episodes.

Since most of these patients are in older age groups, it is important to develop concepts, systems, and devices that can be handled by older patients and meet their individual needs and limitations. Consequently, mHealth concepts need to be evaluated not only for their benefit but also for their feasibility, acceptance, and economic efficiency. Ideally, respective studies should consider research settings close to classical health-care, and should include older patients and patients with cognitive and physical limitations (International Telecommunications Union, 2010).

3. VENOUS THROMBOEMBOLISM

Pulmonary Embolism (PE) and Deep Venous Thrombosis (DVT) represent a widely-spread pathology which has drawn attention due to the increasing incidence and has become the leading cause of death and disability worldwide. VTE does not discriminate. It affects people of all ages, races and ethnicities and occurs in both men and women. Certain factors and situations can increase the risk of developing potentially deadly blood clots (World thrombosis day, 2016). Bone fractures, medical prosthesis, cancer and chronic diseases are some of the main predisposing factors for PE and DVT (Stavros et al., 2014).

On one hand hip, knee fractures or prosthesis are major predisposing factors, increasing the PE risk up to 10 times. On the other hand, cancer and chronic diseases represent intermediary predisposing factors, increasing the risk by 3-10 times. All the predisposing factors act through the Virchow triad: endothelial dysfunction, thrombosis, venous stasis. For instance, patients with cancer have little mobility, thus venous stasis is present in their cases.

Also for all these patients, the presence of neoplasia induces a hypercoagulability state, which favours PE or DVT. It is important to state that up to 30% of patients with DVT or PE do not have any predisposing factor. Most likely for the latter mentioned, the predisposing factor is represented by thrombophilia with an undiscovered genetic defect (Stavros et al., 2014).

The essential factors in diagnosing PE are the clinical probability, considering predisposing factors, the clinical symptoms and the clinical signs. The most used scoring system to calculate the clinical probability is Geneva score.

This score takes into account the history of DVT or PE, the presence of active cancer or surgical procedures (in the past 3-4 weeks) and the age (older than 75 years).

The clinical signs are represented by tachycardia and signs of DVT. The clinical symptoms are represented by pain of unilateral lower limb pain and haemoptysis. This score categorises the clinical probability in low, intermediary or high. The importance of calculating this probability is represented by the imagery and paraclinical investigations needed to confirm or to exclude PE.

During the acute period, the treatment consists of injectable anticoagulants and in some cases thrombolytic agents are used. These therapies are associated with high bleeding risk. That is why before initiating the anticoagulants or thrombolytic therapy the absolute and relative contraindications must be closely verified.

After an acute event, chronic therapy is needed. This includes oral anticoagulants like Vitamin K antagonist anticoagulants (VKA) or novel anticoagulants (N-AC). Both types of oral anticoagulants are associated with an increased risk of bleeding, but N-AC have a safer bleeding profile compared to VKA. Meanwhile N-AC doses are easier to adjust because this medication does not need to be monitored through prothrombin time (PT) as VKA needs.

The anticoagulation period is also different, being related to the recurrence of the acute episode and to the presence of any predisposing factors. The patients with recurrent PE or DVT must be anti-coagulated indefinitely and some of the patients with first episode of DVT or PE can be anti-coagulated indefinitely in the absence of predisposing factors (Stavros et al., 2014; Michael et al., 2011; Samuel et al., 2011).

When considering indefinite anticoagulation, a bleeding score must be calculated. The RIETE score refers to bleeding risk for patients with permanent anticoagulation for PE or DVT. This score considers the age of the patient (bleeding risk increases in patients over 75 years old), the presence of anaemia, severe renal dysfunction and the clinically-overt PE.

It is obvious that for elders and for patients with severe renal dysfunction or anaemia, the bleeding risk associated with permanent anticoagulation is higher, therefore a proper monitoring is required (Ruíz-Giménez et al., 2008).

The role of telemedicine in this context seems to be very important because most these patients have an unhealthy lifestyle, poor mobility and a high bleeding risk. The continuous exchange of information between the medical staff and the patients is mandatory in these situations and can be facilitated using ICT systems that can provide simple and rapid interactions (Elizabeth A. et al., 2014; Loane et al., 2002).

The main role of telemedicine in patients with PE or DVT would be to guide the rehabilitation process after the acute event. Telemedicine can play a very important role in identifying the early signs of a possible recurrence (Elizabeth et al., 2014).

Patients' evolution can be monitored and any dangerous situations can be detected with the help of a medical device capable of transmitting vital parameters in real time.

For example, a drop in oxygen arterial saturation (SaO2) or an increasing heart rate associated with a drop in the blood pressure in patients with history of recent DVT or PE may indicate the recurrence of the disease.

Another important parameter is represented by the breathing rate (BR). An alarm regarding dyspnoea associated with an increased BR and a drop of SaO2 could represent signs of a recurrence.

Many times, bleedings are not obvious for the patients (for example occult gastrointestinal bleedings) that`s why the role of telemedicine would be to constantly assess the bleeding side effects and to advice the patients to pay attention to these reactions (Loane et al., 2002; Donya, 2007).

The above-mentioned situations have conducted us to start a research over the use of a current m-Health solution designed for myocardial infarction cardiac rehabilitation in another setting. This research has involved patients who suffered of PE or DVT.

Because real time communication between the patients and medical team is essential the studied solution has been used to provide means of facilitating the transmission of disease recurrence signs and also the patients' notification about any needed interventions (Terkelsen et al., 2008).

4. REMOTE MONITORING SYSTEM

The previous chapters mentioned a remote monitoring system, which we will discuss more about in the following section. This system's architecture was created so that it provides a real-time interaction between the remote patient and the hospital offering reliability, scalability, data safety and confidentiality (see Fig.1):

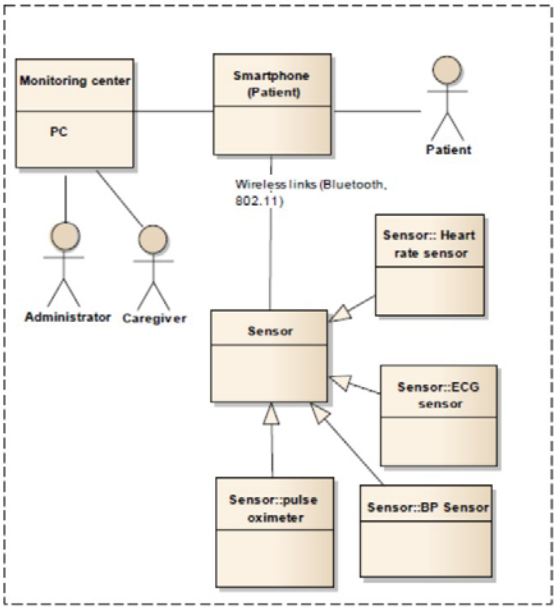

Fig. 1. System architecture.

4.1 Data acquisition

A patient that is enrolled in the remote monitoring process receives the following devices:

A chest strap band that uses Bluetooth to provide heart rate, respiratory rate interval, speed & distance to the mobile devices, with a long transmission range (~300ft up to ~1000ft), logs and stores up to 20 days of data, available GPS module provides speed, distance and location, battery Life: 26 Hours per charge

A pulse-oximeter that measures Oxygen saturation in a display range 0-100% SpO2, pulse rate display range 18 – 321 beats per minute (BPM), with a battery life operating: approximately 600 spot checks and uses a L-shaped PWB whip-type antenna transmitter Bluetooth Compliance: Version 2.0.

An oscillometric blood pressure meter with a measurement range: 20-280mmHg (blood pressure)/40-200 pulse (beats per minute), wireless communication: Bluetooth Ver 2.1, Class 1 SSP, HDP Continua Certified.

The sensors use a Serial Port Profile (SPP) and a Health Device Profile(HDP) for facilitating the wireless communication with a Smartphone. SPP is a Bluetooth wireless transmission protocol often used as a sensor data transmission solution for devices due to its reliability and simplicity.

HDP (Health Device Profile) is a Bluetooth protocol that interacts with the Multi-Channel Adaptation Protocol (MCAP) as well as with the Device ID Protocol (DIP) to provide a reliable solution with features such as service discovery for mobile health devices.

To provide a real-time system for data acquisition, an engine based on these two main modules was designed consisting of a Sensor Data Acquisition (SDA) and the Local Data Storage (LDS).

The SDA is the module that handles data transmission from the monitoring devices to the mobile smartphone. Whenever a measurement is to be made by the patient, a Bluetooth discovery is sent from the Smartphone in order to find the corresponding available device from which it should receive data.

A communication link through Bluetooth pairing is established when such a device is found. This communication link differs from device to device: the chest strap band uses its own data acquisition protocol IEEE 802.15.4, the pulse-oximeter uses both IEEE11073 - Health Device Profile, Continua Alliance and SPP for data acquisition, the blood pressure meter uses HDP.

A testing routine is triggered before starting the data acquisition. The tests check whether the smartphone has the Bluetooth device switched to ON, whether there is a paired link between the phone and the selected measuring device, whether the SDA is ON.

4.2 Patient's interface

Patients interface was created as simple as possible to promote an easy access to all its functionalities no matter the age of the user.

To ensure confidentiality when accessing it there is a login zone. After logging in it becomes active until you exit the application.

In the application, the alarms are the most frequent icons to ensure fast access from every zone.

Besides the alarms zone the graphical interface also offers the user the possibility of engaging in an assisted exercise programme. The patient has to select from different types of exercises while wearing the health measuring devices. During these exercises, information about one's health parameters can be seen.

The third option that the graphical interface offers is related to the one in which the patient must measure several health parameters two times per day.

Two other options are present in the graphical interface. One in which the user can visualise the advices sent by the doctor and another one in which the user can see the measurement's history for the past week.

4.3 The System Back-End

The system's components are based on web services and the communication between them uses REST (Representational State Transfer). In the REST architectural style, the data as well as the functionality are considered resources and are accessed through URIs (Uniform Resource Identifiers). Resources are controlled using several operations such as read, update and delete which are made possible through HTTP PUT, GET, POST and DELETE methods.

The resources can be represented in a series of formats when using REST but for the system we are using, the resources format used is JSON.

Above everything else, the confidentiality and integrity of all that is being sent inside this system are essential. No one intercepting this communication should be able to see the data or to change it. For this reason, the system uses OpenVPN which is an open source application that make use of virtual private networks (VPN) in order to provide secure site-to-site connection over the Internet. The system's VPN uses authentication through certificates.

The central part of the system is in the cloud infrastructure, which was deployed using OpenStack. OpenStack represents open source software for creating and controlling large numbers of compute, storage and networking resources.

Several machines were deployed in this infrastructure; all of them use Ubuntu 14.04 LTS operating system, two of which are important components in the data flow. One of the machines runs Java code to serve as a web service, which defines several thresholds for the received patient's measurements. If the measurements' values exceed the threshold alarm messages are being sent both to the doctor and the patient.

Both the measurements that are below or above the thresholds are sent to the database service which is the other important machine deployed in the cloud infrastructure. This machine uses MySQL server and it maintains information about the users, their measurements, alarms, users' authentication, etc.

4.4 Doctor's interface

The doctor's application was developed using C# 4.5 framework, Telerik library and WPF (Windows Presentation Foundation) for the GUI (Fig 2).

The implementation uses MVVM (Model-View-View Model) architectural pattern. The requests for data from the database are implemented using Repository pattern, whereas for the object's inheritance inside the code, Factory Pattern was used.

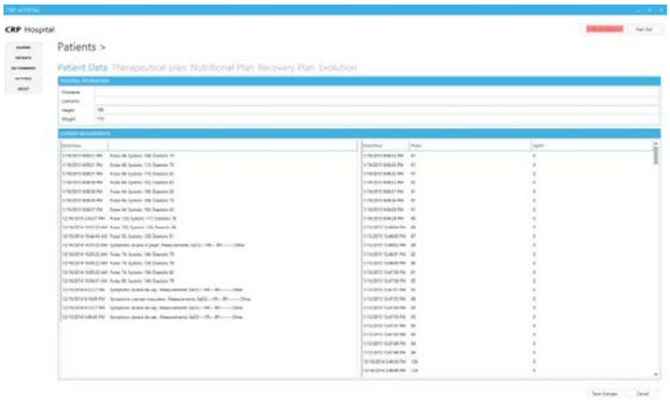

Fig. 2. Doctors Desktop interface.

This application provides the doctor with the possibility of seeing patient's alarms and vital stats and react on them (acknowledge them). The doctor can choose to see the patient's evolution through charts and has also the possibility of prescribing medication, nutrition advice, or advice regarding the patient's training intensity.

5. EXPERIMENTAL SECTION

5.1. Subjects

Patients aged between 40 and 74 years old were recruited and enrolled based on their free consent in the VTE monitoring study designed in the Cardiology Department of Bagdasar Arseni Emergency Hospital at Bucharest, Romania.

The study took place between January 2015 and June 2016. Selected patients were recently discharged from the hospital following a VTE event (DVT or a PE). They were all on anticoagulation medication with the same novel anticoagulants (N-AC). The exclusion criteria were total mobility impairment, inability to use the devices following the training phase and serious psychiatric comorbidity.

Following randomization 31 patients were assigned to the remote monitored group (RMG) and used the proposed ehealth system another 31 were assigned to the control group with no ambulatory monitoring(CG). All participants gave their informed consent for participating within the clinical trial.

5.2. Study design

The study was designed with two medical visits for both studied groups (See Table 1.)

During the initial assessment, a complete clinical investigation was performed to certify the hemodynamic stability of the patients. This comprised of a clinical examination, ECG, echocardiography, venous Doppler echography. A 6-minute’s walking test was performed for each patient to quantify their cardiorespiratory fitness. The remote monitored group received the monitoring devices consisting of the Smartphone, blood pressure measurement device, pulse oximeter and ECG chest strap band and instructions on how to use the devices (see Fig. 3).

Table 1. Medical visits and training for both groups

Group	RMG	CG
VISIT 0 Initial assessment	X	X
System use tutorial - Day 1	X	-
System use tutorial - Day 2	X	-
System use tutorial - Day 3	X	-
System use tutorial - Day 4	X	-
System use tutorial - Day 5	X	-
Visit 1 Final assessment – 3 months	X	X

Fig. 3. Patients' initial training.

The control group received instructions on how to manage their condition at home and how to react in case of signs of emergencies. They were offered the possibility to participate at one hour a day training program, up to 5 days following enrolment into the clinical trial. The tutorial consisted in teaching them in performing daily measurements of the vital parameters with the devices, and whenever feeling characteristic symptoms or signs such as dyspnoea, tachycardia, fatigue, swelling of the legs, mobility problems immediately trigger a manual alarm and to monitor O2 saturation and heart rate during these episodes. (See Table 2). A drop in O2 saturation and an increased heart rate could suggest a possible recurrence of TVE.

Table 2. Vital parameters daily monitoring plan

Compulsory measurements	Blood Pressure (BP)	Heart Rate (HR)	Pulse Oximeter (Pulse, SaO2)
Morning	X	X	X
Evening	X	X	X

The monitoring duration for both groups was of 3 months and it was performed in cycles of 7-8 patients, with the second visit consisting of the same medical investigations, needed to evaluate the medical evolution. The event recurrence rate, the bleeding side-effects and treatment compliance of both groups has been assessed.

5.3 Data and statistical analysis

Collected medical data was stored in the private server located within the Cardiology Department. The analysis was performed in the offline mode after the monitoring period ended. There were some cases where data missed due to the following: (1) connectivity problems (2) battery problems, (3) application crash and because of the (4) patient that forgot to take the measurement. The Statistical Package for the Social Sciences (SPSS) and Microsoft Office EXCEL was used for the statistical analyses. The results are described in terms of mean (SD) or percentage.

6. RESULT AND DISCUTION

6.1 Study groups description

The remote monitored group consisted of 31 patients (19 female, 12 male) with an average age of 59 years old and the control group of 31 patients (22 female, 9 male) average age 57 years old, with their characteristics presented in Table 3.

Table 3. Study groups descriptive statistics.

Descriptive Statistics					
CG/RMG		Minimum	Maximum	Mean	Std. Deviation
CG	Age (years)	45	70	59.48	6.612
	Height (meters)	1.6	1.8	1.7129	0.06798
	Weight (Kg)	63	96	78.55	9.75
	BMI (KG/M2)	21.80	33.59	26.76	2.94
	Smoking incidence	0	1	0.97	0.18
	Prolonged immobility	0	1	0.55	0.506
	Supplemental estrogen	0	0	0	0
	Cancer	0	0	0	0
	Surgery	0	1	0.13	0.341
RMG	Age (years)	40	74	57.71	8.498
	Height (meters)	1.56	1.85	1.729	0.07124
	Weight (Kg)	64	95	75.84	9.74
	BMI (KG/M2)	19.71	30.12	25.31	2.22
	Smoking incidence	0	1	0.74	0.445
	Prolonged immobility	0	1	0.23	0.425
	Supplemental estrogen	0	0	0	0
	Cancer	0	0	0	0
	Surgery	0	1	0.19	0.402

Following the Chi-square test analysis between the studied groups and their gender there was no statistical significance P>0.05. (see Table 4)

Table 4. Chi square test analysis study groups and sex.

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	.648[a]	1	.421		
Continuity Correction[b]	.288	1	.591		
Likelihood Ratio	.650	1	.420		
Fisher's Exact Test				.592	.296
Linear-by-Linear Association	.638	1	.425		
N of Valid Cases	62				

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is

b. Computed only for a 2x2 table

By this, the null hypothesis that stated that the groups were identical has been accepted and subsequent evaluations could be performed on both groups.

The patient's weight evolution was monitored during the 3 months period. There was noticed a mean overall bodyweight reduction of about 3.8% reduction in the RMG group ($p<0.05$) and an increase with 0.77% in the CG ($P<0.05$). (See Table 5,6).

Table 5. Weight evolution study groups.

CG/RMG		Mean	N	Std. Deviation	Std. Error Mean
CG	Initial weight (Kg)	78.55	31	9.750	1.751
	Final weight (Kg)	79.16	31	9.431	1.694
RMG	Initial weight (Kg)	75.84	31	9.740	1.749
	Final weight (Kg)	72.94	31	9.266	1.664

Table 6. Weight evolution study groups Paired Samples Significance Test.

Paired Samples Test							
		Paired Differences					
					Confidence		
CG/RMG		Mean	Std. Deviation	Std. Error Mean	Lower	Upper	Sig. (2-tailed)
CG	initial-final weight	-.613	1.520	.273	-1.171	-.055	.03234
RMG	initial-final weight	2.903	2.413	.433	2.018	3.788	.000000202

The cardiorespiratory evolution analysis revealed a mean increase in the 6 minutes walking test distance with 6.8% ($p<0.05$) in the RMG and a decrease with 2.4% of the walking distance in the CG ($p<0.05$). (See Table 7, 8).

Table 7. "6 minutes" walking test results mean evolution.

CG/RMG		Mean	Std. Deviation	Std. Error Mean
CG	6 minutes walking test distance initial(meters)	414.52	64.15288	11.52220
	6 minutes walking test distance final(meters)	405.65	65.73611	11.80655
RMG	6 minutes walking test distance initial(meters)	425.81	57.90937	10.40083
	6 minutes walking test distance final(meters)	455.61	61.44085	11.03510

Table 8. "6 minutes" walking test Paired Samples Significance Test.

Paired Samples Test							
		Paired Differences					
					Interval of the		
CG/RMG		Mean	Std. Deviation	Std. Error Mean	Lower	Upper	Sig. (2-tailed)
CG	initial-final 6 minutes walking test	8.87097	12.15934	2.18388	4.41089	13.33105	.000322
RMG	initial-final 6 minutes walking test	-29.80645	21.78290	3.91232	-37.79648	-21.81642	.000000017

6.2 VTE events

From the RMG there were triggered 24 alarms from a total of 6 patients, regarding acute dyspnoea from which 23 were false alarms. A positive alarm was encountered in a female, 60 years old with left hip prosthesis that had a recurrence of PE, as revealed by CT scan.

The patient had abnormal vital stats, a decreased SaO2: 90% and an increased heart rate (118 bpm). The emergency department has been notified and she was brought at the hospital were the presence of the PE recurrence was diagnosed using the CT scan. No recurrence of DVT was encountered in the monitored group.

From the control group, only one patient presented at the hospital at the final visit with signs of recurrent DVT at the level of the left calf. Doppler ultrasound images revealed popliteal vein blood clot.

6.3 Anticoagulation side effects

No minor or major bleedings were observed in the RMG.

In the CG 3 patients had minor bleedings which were clinically evaluated as a drop of 0.5, 0.6 and 1g/dl of the haemoglobin level at the 3 months revaluation. The bleedings were represented as follows 2 gum bleeding and a rectoragy case (secondary to a colonic polyp).

6.4 Monitoring system use learning curve

The learning curve of using the application was as expected with the proportional increase in the needed day depending on the patient's age. There were no cases of patients requiring more than 5 days of one hour training (see Fig. 6).

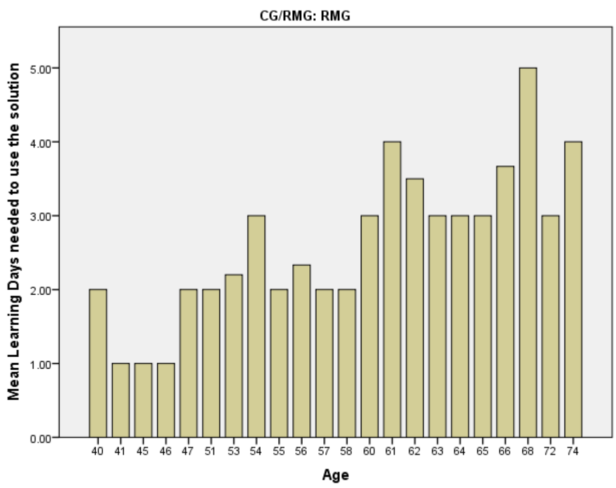

Fig. 6. RMG-Days needed to learn in how to use the mobile app.

6.5 Technical errors reported

The most frequently errors reported from patients from using the monitoring system were: application sudden crashes 13 errors, battery depletion 30 errors, connectivity problems 45 errors problems.

7. CONCLUSIONS

The main scope of the study was to assess the health benefits obtained by using an ehealth solution for monitoring early hospital discharged patient that suffered of an acute PE or DVT event.

In comparison with the unmonitored group of patients the remote monitored group had improved their weight and their cardiorespiratory fitness levels.

It seems that by using the ehealth monitoring solution with a closer interaction with their caregiver, the patients from the remote monitored group became more aware of their medical condition and became more active towards implementing a healthy lifestyle.

A prognostic model and a personalised rehabilitation plan in these patients can be useful for a greater reduction of the risk factors. This is a sector were telemedicine can improve more the patients self-management process with support systems for triggering different alarms and notifications during patients monitoring process that can have the role to remind the patient the importance of healthy habits and to guide the patient in the direction of reduction of his cardiovascular risk factors.

The anticoagulation treatment is a very important issue as more and more patients need permanent anticoagulation and the bleeding risk increases with age and with other comorbidities. Therefore, another secondary objective of the study was to see if by telemedicine we can identify faster the side effects related to the anticoagulation therapy and to adjust the medication. Fortunately, in the remote monitored group there were no minor or major bleedings.

By using the remote monitoring system, a case of PE recurrence was detected very fast. This represents a very important outcome because the intervention time was reduced and a life-threatening event has been avoided.

Unmonitored patients that suffered minor bleeding events didn`t seem to give attention to this events and to report such a problem because they had to get to the hospital for that. None of them presented at the hospital until the 3-month final assessment.

Real time monitoring using telemedicine can play an important role in monitoring patients after PE and DVT regarding the bleeding risk, the compliance to treatment and sometimes even a vital role in identifying early recurrence of the pathology.

Although the average age of the patients was around 60 years at the ease of use analysis we can say that they all managed to learn to use the mobile solution in a reasonable time. The technology is needed also in the older population and when it comes into learning how to use it, if the solutions are built with a friendly simple interface than using it becomes a very easy task.

During the testing of the solution patients encountered some technical problems such as application sudden crash, battery depletion and connectivity problems. The application sudden crashes have been resolved during the application refinement process. The battery depletion errors were solved by introducing a more frequent battery discharge notification. The connectivity problems couldn`t be solved due to the devices internal errors. Further development of the mobile solution and advancements in the field of wireless sensor technology and mobile devices should overcome these issues in future telemedicine monitoring and treatment.

In our opinion these initial observations provide a good starting point for designing more complex telemedicine interventions that aim to empower the patient and to improve the self-management process.

The obtained results demonstrate that there is a real benefit from using monitoring solution for patients that suffered of a VTE and the data gathered are helpful for the future development of mobile apps that aim at improving the prevention programs.

An important drawback of the study has been the reduced number of monitored patients. This limitation appeared due to the limited monitoring sets and because of the short enrolment phase that took place in only one medical site.

Our plan is to extend the number of monitored patients within the study to demonstrate the observed benefits of telemedicine monitoring in terms of health costs reductions, reducing the anxiety levels of the patients and increase their quality of life. Furthermore, we aim also at introducing special prognostic models that based on the patients vital parameters to guide them through the improvement of their risk factors profile.

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