31st Annual International Conference of the IEEE EMBS
Minneapolis, Minnesota, USA, September 2-6, 2009

Technical and Compliance Considerations for Mobile Health Self-monitoring of Glucose and Blood Pressure for patients with Diabetes

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Abstract— **Self-monitoring of blood glucose is an integral part of diabetes care which may be extended to other biometrics. Cellular and short range communication technologies will be important for the routine usage of these systems. However, the issues of follow-up and patient compliance with these emerging systems have not been yet studied evaluated but could be critical to the adoption of these technologies. We evaluated the impact of mobile telemonitoring on the intensification of care on blood pressure control and exposure to hyperglycaemia in patients with diabetes. We randomised 137 patients with diabetes to either mobile telemonitoring (n=72) or usual care patients (n=65) for 9 months. In this paper we present some of the clinical results with focus on blood pressure control hypertension and highlight some of the technical and compliance issues that were encountered.**

Keywords **:** m-health, telemedicine, mobile diabetes care, chronic disease management

I. Introduction

M-health system has been defined as combination of "mobile computing, medical sensor, and communications technologies for health-care'' M-health is increasingly being considered as part of the chronic disease management solution for diabetes. [3]. Self monitoring of blood gloucose (SMBG) together and blood pressure constitute an important part of diabetes care. From the technological view-point recent years have witness extensive research in system addressing the design and development of mobile diabetes management [3,4].

Hypertension is a modifiable risk factor for premature cardiovascular death and micro vascular complications in patients with diabetes [5]. In the past five years the attainment rates of treatment targets for diabetes and blood pressure control in the United Kingdom have increased. The recommendation for the earlier and more intensified use of a wider range of agents have contributed to this improvement [6]. However, the gains in quality of care have not been uniform, with patients from lower socioeconomic and minor ethnic backgrounds benefiting least [5,6]. These disparities probably reflect the ongoing challenges of providing patients with better access to, and involvement in their own care. The remote monitoring of patients is considered an important tool in facilitating improvements in diabetes care. A systematic review has confirmed the feasibility of this approach although questions remain regarding its efficacy on diabetes control and the impact on blood pressure management is unknown [7-10]. In this paper we discuss the technical and compliance challenges relevant to the application of m-health technologies and their wider deployment issues in the NHS based on a clinical trial using this technology.

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II. Mobile Chronic Disease Management System

The system used in this clinical study is shown in Fig. 1. The basic architecture and technical details of the m-health system for capturing measurements of blood glucose and blood pressure is described elsewhere [3]. The system is structured into three main elements:

(i) The patient end that contains the mobile terminals powered with short range wireless Bluetooth™ connectivity with the allocated blood glucose and blood pressure devices.

(ii) The web interface and patients journals that can be accessed securely by the specialist nurse or the doctor to provide them with web access of their patients' health, their wireless telemedical and management tools and alerts. There is also the web based patient journal that can allow the patient to interact with the specialist nurse on their progress.

(iii) The system server and central data management system.

In this system, the patient data was transmitted to the hospital using (3G) cellular network connectivity for accessing the server data with secure encoded data links via a tailor made disease management web system based on Motohealth™ technology. The 3G mobile terminals used in the study (Motorola A1000) and were configured to show the accumulated or individual measurements and could also is used to contact the clinical research team for clinical and technical support.

Patients in the m-health arm were trained to self-measure capillary blood sugar using a monitor (One Touch Ultra Glucose Meter, Lifescan, CA, USA). Blood pressure was measured twice after 10 minutes rest using a digital monitor (A&D Medical, UA-767BT, CA, USA) in the non-dominant

arm positioned at heart level by the research nurse. Patients in the intervention arm were trained to self-measure their blood pressure at home using the same device and transmit their recordings wirelessly by Bluetooth™ wireless technology to the 3G mobile terminals. Recordings were performed weekly. The mobile phone signaled when a measurement was due within a 2 hour window of the agreed measurement time. The wireless capillary blood glucose tests were also requested between 4 and 9 times/ week. Patients were randomized to the m-Health (MH) or usual care (UC) groups according to computer generated random number sequence (Stat Mate™ 1.01i CA, USA).Those in the UC group received their care from the diabetes centre and/or the local practitioners according to normal practices. The study was approved by the Wandsworth Ethics Committee and all patients provided written informed consent.

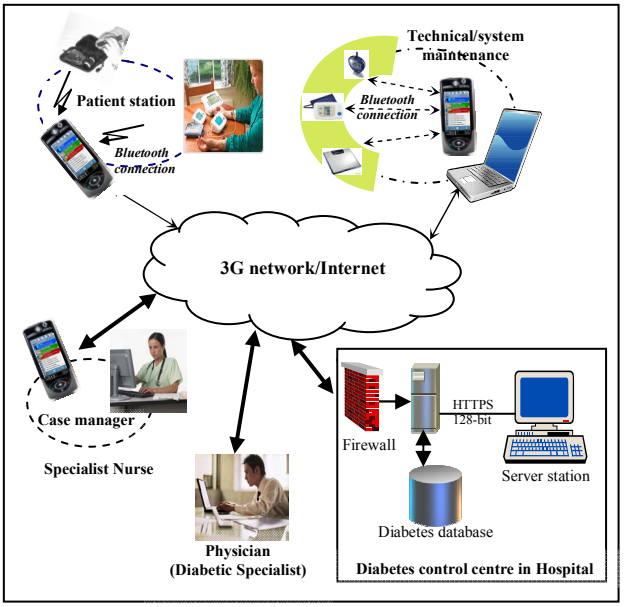

Fig.1 M-health Management System for the trials

III. Patients And Methods

The study was based at the Thomas Addison Diabetes Centre at St George's Hospital in South London, UK which serves the inner-city population characterized by a diverse ethnic mix 22% of residents belong to a non-white minority ethnic group and a social deprivation score is higher than national average (www.capitalambition.gov.uk/documents). Eligible patients were invited to take part in the randomized parallel group study between December 2006 and July 2007. Ambulant patients >18 years of age with a known diagnosis of diabetes and either receiving treatment for hypertension or with an untreated blood pressure > 130/80 mmHg were eligible. Exclusion criteria were a physical inability to self-monitor blood glucose or blood pressure, pregnancy, severe life threatening or terminal illness and inability to provide written informed consent.

A standardized diabetes data set was collected for each patient on proformas and transferred to an electronic database for later evaluation. Body Mass Index (BMI) was calculated from weight in kilogrammes divided by height in meters squared. Diabetic retinopathy was screened for using digital fundus photography after pupil dilatation and recorded as present (background, pre-proliferative or proliferative) or absent.

Fasting venous blood was taken from an antecubital vein. Hemoglobin A1c was measured by High Performance Liquid Chromatography (HPLC) (Menarini 8140, UK). Total- and HDL-cholesterol and total triglycerides were estimated using enzymatic methods (Boehringer-Mannheim, Germany). LDL-cholesterol concentration was calculated using the Friedewald formula: LDL cholesterol = Total cholesterol-(Triglyceride (mmol/L) / (2.19) - HDL-cholesterol (mmol/L). Urinary albumin and creatinine were measured by immunoturbidimetry (Cobas Fara, Roche) and the Jaffe rate reaction methods respectively.

Analysis between or within the groups were performed using SPSS 16.0 for Windows (Chicago, USA). Continuous variables were compared using parametric or non-parametric tests and associations tested with Spearman's rank or Pearson's test according to their distribution. Categorical variables were compared using Chi-squared with continuity correction or Fisher's Exact test. Data are expressed as mean (standard deviation) unless otherwise stated.

IV. Results And Discussion

We identified 4569 (54% male) patients with diabetes from the registers of 26 practices in South Wandsworth, London, UK. Ten percent had a diagnosis of type 1 diabetes, the mean age was 61 years and the proportion of White, Black (African and or Caribbean) or Asian (Indian, Pakistan or Bangladeshi) heritage was 41, 23 and 35% respectively. A sample of 137 patients who were representative of the population with diabetes provided informed consent and were randomized to either the MH intervention (n=72) or UC (n=65) control groups.

In each group, 29 patients had a record of diabetic retinopathy, 5% were treated with diet alone and 25% with insulin alone as the main management modality for diabetes. The groups were well matched according to their demographic characteristics and baseline blood pressure, HbA1c, renal function and lipid profile as shown in Table1.

Patients in the mobile health (MH) group sent a total of 1721 blood pressure, and 4099 blood glucose readings over a period 7.5(5.0) months. The transmission rate of blood pressure recordings (4.0 [3.8]/person/month) was consistent with the protocol whereas that for blood glucose (1.8[1.1]/person/week) was significantly less than expected (p=0.0001). Patients whose averaged home systolic blood pressure was <120 mmHg also had significantly lower average capillary blood sugars as shown in Fig. 2.

Table 1. Baseline demographic, clinical and biochemical data of patients with diabetes randomized to the m-health (MH) intervention or usual care (UC) control group

	MH	UC	p
N	72	65	
Age (years)	59.6 (12.0)	57.1(13.0)	0.25
Duration of diabetes	13.3 (8.6)	11.7 (8.0)	0.27
Type 1 diabetes *n* (%)	6 (8)	5 (8)	0.85
Type 2 diabetes *n* (%)	66 (92)	60 (92)	
Weight (kg)	79.7 (17.9)	80.1 (20.1)	0.91
Ethnic group *n* (%) :-			
Caucasian	26 (36)	21 (32)	
African-Caribbean	24 (33)	18 (28)	
Indo-Asian	21 (29)	21 (32)	0.79
Other	1 (1)	5 (7)	
HbA1c (%)	7.9 (1.5)	8.1 (1.6)	0.4
Total cholesterol (mmol/l)	4.3 (1.1)	4.4 (1.2)	0.76
Total triglycerides (mmol/l)	1.5 (0.8)	2.1 (2.7)	0.1
HD-cholesterol	1.2 (0.4)	1.2 (0.4)	0.81
LD-cholesterol	2.5 (0.9)	2.5 (0.9)	0.92
Plasma creatinine (µmol/l)	111.1 (102.1)	93.0 (43.1)	0.21
Systolic blood pressure (mmHg)	130.5 (15.1)	131.8 (19.7)	0.67
Diastolic blood pressure (mmHg)	76.9 (9.4)	76.6 (11.3)	0.82

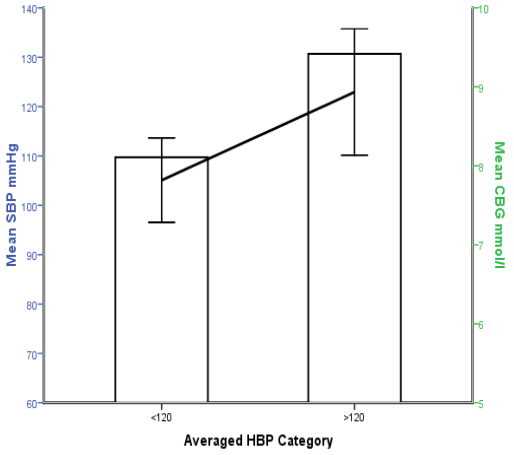

Fig.2 Averaged systolic blood pressure verse blood sugars with respect to averaged home systolic blood pressure

After 9 months the patients were reassessed with repeat blood pressure and HbA1c measurements. The within group analysis showed a mean [95% confidence interval] significant fall in systolic blood pressure (SBP) in the patients in the MH group (-6.5[-0.8 to -12.2] mmHg ;p=0.027) but not in the UC control group (2.1[9.3 to -5.0] mmHg; p=0.57).

The mean decrement in SBP was greatest within the patients of African-Caribbean heritage as shown in Fig. 3.

The effect of the intervention in the MH group was confirmed by sensitivity analysis which showed significant drop in SBP of -2.9 [0.6 to – 5.1] mmHg; p = 0.013. There were no significant changes in diastolic blood pressure, HbA1c or cholesterol profile in either group.

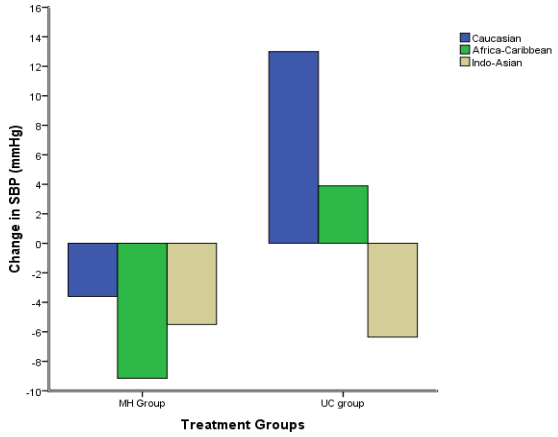

Fig.3 Clinical results of lowering the blood pressure levels using m-health system compared to usual care according to ethnic group.

These results show that mobile telemonitoring is an effective method for reducing blood pressure in patients with established diabetes, hypertension and microvascular complications. Patients who achieved lower blood pressures also appeared to benefit from less exposure to hyperglycemia. Our work suggests that the potential benefits of this approach may be generally applicable and could empower those at high risk of complications who experience most health inequality [11]. The impact of home blood pressure monitoring is dependent on the support patients receive from their healthcares otherwise the effects can be modest [12]. The study was not powered to identify factors which would explain the differential blood pressure responses between the ethnic subgroups. However, there were several issues that need further studies to confirm these findings for further larger scale deployment:

1- The patient compliance and follow-up by the specialist nurses and their continued use of the measurements during the clinical study period.

2- The communication challenges and connectivity issues

between medical devices and the mobile terminals was a major problem that impacted patient satisfaction with the system.

3- The lack of the compatibility of the system with different mobile operating systems and terminals.

5- Security issues of sending the medical data was not addressed in this study and further work is needed in this important area in the future.

6- The standardizations of these technologies and the interoperability issues. These are currently being addressed within the Continua Health Alliance for the relevant IEEE standards for the medical devices. However, there is more work to be done on these issues potentially for each disease management system and requirements.

These issues are important yet pending challenges that need to be addressed in any future design and further technical refinement of these systems with successful and reliable large deployment healthcare services

V. CONCLUSION

In this paper we have shown that mobile telemonitoring is an effective method for reducing blood pressure in patients with established diabetes, hypertension and microvascular complications. Patients who achieved lower blood pressures also appeared to benefit from less exposure to hyperglycemia. We also highlighted some of the technical and compliance challenges that face such systems. Further quantitative and qualitative analyses of similar clinical trials will be insightful in understanding the patient with diabetes' attitudes and for the future and longer-term use of the mobile technologies in their care plan.

ACKNOWLEDGMENT

The authors would like to acknowledge the financial support and funding of Motorola, USA the IDEN group and Motorola, UK for this project and clinical trials. Acknowledgments also to the nursing and medical team of Dr. Ken Earle from St. George's medical school and NHS Trust in London for the provision of clinical data of this study.

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