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A new digital health tool for the telemonitoring of patients with scleroderma during iloprost administration: a feasibility and acceptability study

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Abstract. – OBJECTIVE: To assess the feasibility of a new device for telemonitoring vital parameters during iloprost infusion.

MATERIALS AND METHODS: In a pilot study, patients with systemic sclerosis received iloprost infusion while being telemonitored with Umana T1 Heart Monitor, within the hospital, under the supervision of family/community nurses and rheumatologists. Patients were administered a questionnaire to obtain information on satisfaction, practicability, and compliance with the new monitoring device.

RESULTS: Data recorded by the device for blood pressure, heart rate, and oximetry were concordant with those registered directly by nurses. Most patients found the device useful and thought it could be used at home, even while working.

CONCLUSIONS: Umana Heart Monitor T1 could be a valuable aid in at-home iloprost therapy in patients with systemic sclerosis.

Key Words:
Iloprost, Scleroderma, Telemonitoring, Infonde, Umana T1 heart monitor.

Introduction

Systemic sclerosis (SSc) is an autoimmune disease characterized by vasculopathy, activation of the immune system, and tissue fibrosis[1]. Raynaud's phenomenon (RP) occurs in approximately 95% of patients. Digital ulcers, which are mainly related to severe RP and represent the leading cause of disability, are found in 5-10% of cases[2,3]. The treatment of these vascular manifestations of SSc is based on the use of calcium channel blockers, such as bosentan, cilostazol, antiplatelet agents, sildenafil, and the antiplatelet iloprost[4-6]. Iloprost is a hospital drug administered by intravenous infusions. It requires monitoring blood pressure and heart rate during drug titration, with closer monitoring in hypotensive patients or with heart diseases. Since the introduction of the wearable syringe pump Infonde® (Italfarmaco S.p.A., Cinisello Balsamo, Milan, Italy), allowing autonomy of movement and management, at-home infusion has become possible. Indeed, home therapy with iloprost administered by a wearable syringe pump was approved by the Italian Drug Regulatory Agency (AIFA) in 2021[7,8]. This new approach is in line with the growing interest in telemedicine. In 2020, the Italian Ministry of Health recommended to reorganize the National Health System, particularly at the local level, by implementing digital health tools[9]. Recent experience has shown[10,11] that discontinuation of iloprost treatment due to the COVID-19 pandemic and for logistic reasons has been associated with worsening clinical manifestations of scleroderma, such as RP and digital ulcers.

The efficacy, safety, and feasibility of iloprost administration using the new injection device have been demonstrated by clinical experiences[12-15]. Home therapy with iloprost requires the feasibility of the infusion and the possibility of monitoring blood pressure and heart rate at home. A non-invasive telemonitoring device that is easy for patients to use without healthcare professionals was applied to this setting and used in a pilot

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project based on the collaboration of a specialized hospital center with family/community nurses. The objective of the pilot project was to evaluate patient and professional satisfaction and the feasibility of the telemonitoring device in a hospital setting.

Patients and Methods

The pilot project was designed and led by the Medical Rheumatology Day Hospital of Legnano, Italy (ASST Ovest Milanese – Regione Lombardia) with the cooperation of family/community nurses working in the same Italian region in April 2022. Lombardy Regional Health System has recently legally approved the role of these healthcare professionals; they provide nursing assistance by linking together social and health services operating in the area for out-of-hospital patients. The project has been approved by the local Ethics Committee (Comitato Etico Milano Area 3, approval No. S00089/2022, 06/09/2022).

Patients

Consecutive patients affected by SSc, diagnosed according to the 2013 ACR/EULAR criteria, were enrolled. The included patients had previously tolerated iloprost (no adverse events or mild events managed by nurses or patient) administered by the traditional infusion method and had received cyclic infusion treatment with iloprost for ≥12 months, at intervals of 2-4 weeks, using the Infonde® syringe pump (Italfarmaco S.p.A., Italy), and provided informed consent. The project included telemonitoring of heart function during iloprost infusion, concomitant with direct nursing control, to assess patient satisfaction and feasibility based on nurses' feedback.

Telemonitoring Device

Umana T1 Heart Monitor (Umana Medical Technologies Ltd, Luqa, Malta) is a medical device for collecting and analyzing diagnostic electrocardiograms (ECGs), respiratory rate, body temperature, systolic blood pressure, and physical activity data.

It comprises a small wearable ECG monitor, a dongle medical device accessory for measuring body temperature and oxygen saturation, and two medical device software accessories (Figure 1). The monitor gathers data through the Umana T1 Smarter Skin+ Sensors, a disposable/single-use Class I medical device. Data are transmitted in real-time *via* Bluetooth to its accessory T1 Monitor App installed on a third-party smartphone or tablet. The App transfers the data *via* the Internet (4G or Wi-Fi) to a dashboard accessible to medical professionals by secure credentials that allow them to create alerts based on physician-set threshold values to detect anomalies occurring during iloprost infusion. Healthcare professionals can then download and analyze data with the accessory diagnostic software T1 Biosignals Studio.

Umana T1 Smarter Skin+ Sensors is an ultra-thin, non-invasive, not implantable digital

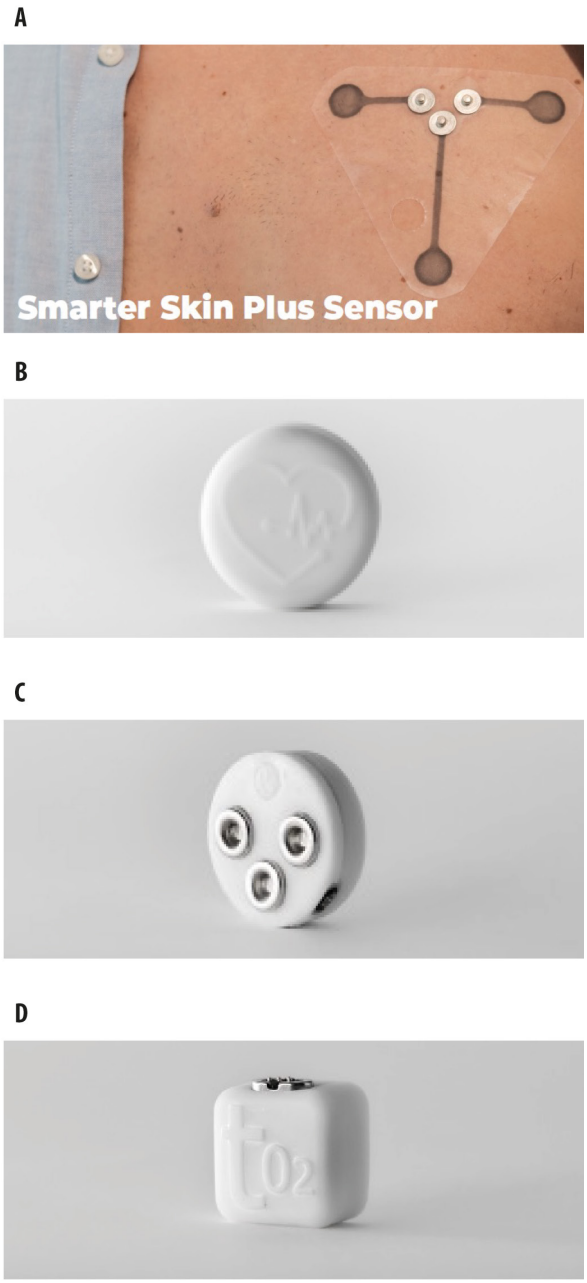

Figure 1. **A**, Umana T1 Smarter Skin+ Sensor; (**B-C**), ECG, temperature, and blood pressure monitor; **D**, oximetry monitor.

patch applied in the third intercostal space, perpendicular to the midclavicular line of the left subclavicular region with any electroconductive paste or gel. The sensor, which requires no electroconductive paste or gel to adhere to the skin, interfaces with TI Heart Monitor through three medical-grade metal magnetic studs for data transmission.

Data are collected and processed by the current laws on privacy. The platform's security level complies with the international standards ISO 27001[16] and according to articles 32 and 33 of GDPR[17].

Monitoring Process

Rheumatologists and family/community nurses were responsible for data monitoring at the day hospital center. The device was applied to patients in the day hospital when iloprost infusion was administered. Patients were allowed to leave the Rheumatology Day Hospital, being free to move through the hospital premises by communicating their location. They were instructed to report any problems actively; the family/community nurses called patients by telephone every 30 minutes and whenever heart parameter anomalies occurred.

Assessment

At the end of the therapy, a questionnaire was administered to patients to get information about satisfaction, practicability, and compliance with the new monitoring device (Table I). Answers were given on a 1-5-point Likert scale. The family nurses recorded the device's functioning, the procedure's feasibility, transmission errors, and subsequent suggestions for improving device management.

The device monitored blood pressure, heart frequency, body temperature, respiration rate, and oximetry; nurses also personally measured these parameters at regular intervals.

Statistical Analysis

This was a pilot study; the reduced number of patients and the absence of a control population did not allow statistical data analysis.

Results

Overall, 40 patients (4 males and 36 females with median age of 46 years, 26-78 years) were included. They had been suffering from SSc for a median time of 7 years, ranging from 1 to 22 years.

All patients completed the 6-hour iloprost infusion except one with asymptomatic atrial fibrillation while being monitored.

The adverse events recorded during monitoring were within those expected during iloprost infusions, such as mild intensity headache and nausea, and did not require discontinuation of

Table I. Questionnaire on patient satisfaction.

Item	At all 1	A little 2	Enough 3	A lot 4	Extremely 5
1. Do you think that the device is useful?	0	0	17	55	28
2. Do you think that it may be used at home?	0	7	12	43	38
3. Do you think that it may improve your adherence to therapy?	5	5	33	45	12
4. Does continuous distance monitoring make you feel safer?	0	7	22	43	28
5. In case of problems, can you stop the infusion yourself?	17	12	0	8	8
6. Can you tolerate the device (plaster) in terms of itching, skin adherence, weight, etc.?	0	10	0	55	33
7. If yes, please describe.					
8. Have you experienced any problems using the App?					
9. Does the device improve your quality of life during the therapy (it facilitates your movements, etc.)?	5	10	20	40	25
10. Do you think you could do some light work while using this device?	5	20	22	48	5
11. Do you think you will go to the hospital less often, thanks to this device?	5	7	45	33	10
12. Are you afraid of being less carefully followed-up because of the device? (Please, note that dedicated nurses and physicians will be available at this time).	12	25	22	20	30

Answers were scored on a 5-point Likert scale. Numbers represent the percentage of responses per score.

therapy or medical intervention. No episodes of hypotension, hypertension, oximetry desaturation, changes in body temperature, or significant rhythm disturbances (except one case of atrial fibrillation) were recorded.

Parameters Recording and Nurses' Opinion on Usability

Data recorded by the device for blood pressure, heart rate, and oximetry were concordant with those registered directly by nurses. Temperature monitoring was not considered consistent by the nurses.

Although nurses suggested that the dashboard visualization should be facilitated, they stated that the device is easy to use and has good potential to simplify patient monitoring during infusion. Alerts on parameter monitoring were only sometimes timely due to Bluetooth connection problems, especially when patients moved away from their smartphones.

Patients' Opinion

The frequency of answers to the questionnaire is reported in Table I. Briefly, more than 80% of patients rated the telemonitoring system during iloprost administration as useful or very useful, and almost 80% thought the device could be used at home and improve adherence to therapy. The device was felt to improve a lot or extremely the perception of the safety of the infusion by 70% of subjects. Nevertheless, only 17% of patients answered that they could manage the device well or very well. The device was well tolerated (88%), and more than 80% of subjects thought it could improve their quality of life during infusion, at least "enough"; 70% of subjects felt they could work while using the device. The proportion of patients expecting a great or very great reduction in hospitalizations was only 43%, and 50% of subjects feared being less carefully assisted if telemonitoring was used routinely.

Discussion

This article describes a pilot experience using a device for telemonitoring heart function during iloprost administration with a syringe pump in patients with SSc. Limitations of the study are the reduced number of patients and the absence of a control population, which does not allow statistical data analysis. Nevertheless, we can derive important information from the study, knowing that SSc is a rare disease, and a controlled study is not feasible in this setting.

Telemonitoring of heart rate and blood pressure under the responsibility of dedicated home care nurses is functional for the home administration of iloprost, which has recently been approved in Italy to improve patient quality of life while reducing costs and burden on the health system. Logistic reasons (e.g., distance from the hospital and lack of seats for infusions) are the main causes of therapy interruption. Recent publications[10,11] have highlighted that discontinuation of iloprost is associated with acral manifestations worsening.

Our experience has shown that patients tolerate the skin sensor well, data transmission is satisfactory, and the dedicated App is easy to use. Nurses found that the assessment of parameters through the telemonitoring device is reliable (except for body temperature, which seems little important in this setting); in their opinion, this system can enable early diagnosis of arrhythmias and hypertensive crises. One patient had atrial fibrillation during iloprost infusion, and the telemonitoring enabled prompt detection, followed by immediate discontinuation of the infusion and referral of the patient to the emergency department. The system allowed an easy assessment of oximetry and the execution of the gait analysis, which is particularly difficult in scleroderma patients. Although temperature monitoring is not very important, a new sensor with a higher sensibility for temperature measurement is being developed.

The prolonged duration of infusion therapy in the hospital setting has been shown[8] to negatively impact patient perceived satisfaction, resulting in reduced adherence.

The patient opinion on telemonitoring using T1 Heart Monitor was positive in terms of tolerability, quality of life improvement, and perception of the safety of iloprost infusion. These results may encourage the implementation of home treatment, given interventions aimed at improving adherence. Indeed, our results open the possibility of routine use of home administration of iloprost in SSc patients with the help of telemedicine. Possible advantages for patients include reducing working day loss, saving travel costs for those who live far from specialized clinical centers, and improved quality of life with reduced risk of hospitalization. Family/community nurses would acquire high professional skills and enhanced experience in engaging with chronic patients. Thanks to telemonitoring, cost reduction for fewer hospitalizations could outweigh the telemonitoring

costs. A possible reduction in healthcare expenditures is advisable when resources are considered insufficient for the growing needs due to several factors, such as the recent pandemic and the increasing population age.

Conclusions

This pilot project on the use of the Umana Heart Monitor T1 for remote telemonitoring during infusion therapy with iloprost in patients suffering from SSc suggested that this approach is feasible in terms of tolerability, patient acceptance, safety, and reliability of the evaluation. This digital health tool and wearable Infonde pump could be a valuable aid in at-home therapy.

Conflict of Interest

RP was employed in Italfarmaco when the study was performed. The other authors have no conflicts to declare.

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Ethics Approval

The project has been approved by the local Ethics Committee (No. S00089/2022, 30/08/2022). The study was performed in accordance with the World Medical Association Declaration of Helsinki (2013).

Informed Consent

All enrolled patients released written informed consent.

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