Κωνσταντινίδης Δημήτρης
Καρδιολόγος
Επιστ. Συνεργάτης Μονάδας Υπέρτασης
Ά Πανεπιστημιακή Καρδιολογική Κλινική
ΓΝΑ Ιπποκράτειο

MOBILE HEALTH ΣΤΗ ΔΙΑΧΕΙΡΙΣΗ ΤΗΣ ΥΠΕΡΤΑΣΗΣ: ΠΑΡΟΝ ΚΑΙ ΜΕΛΛΟΝ

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Conflict of interest: NONE
THE REAL LIFE

Despite the number of currently available effective therapies, the burden of disease caused by hypertension has been constantly growing over the last 10 years.

- 1 billion people worldwide are hypertensive
- About 20% of adults with hypertension are unaware of the diagnosis
- Only 50% of the hypertensive population is controlled by therapy with 3 main causes:
  1. physician inertia,
  2. patient low adherence to treatment,
  3. deficiencies of healthcare systems in their approach to chronic diseases

These data shed light on the opportunities for improvement in hypertension diagnosis, patient awareness, and control rates in all populations and especially those with limited access to health care.
DEFINITION OF M-HEALTH (4G HEALTH)

- The term m-Health was coined by Robert Istepanian as use of "emerging mobile communications and network technologies for healthcare"
- It means the practice of medicine and public health supported by mobile devices (mobile phones, tablet computers and PDAs, and wearable devices such as smart watches, for health services, information, and data collection)
- eHealth can largely be viewed as technology that supports the functions and delivery of healthcare, while mHealth rests largely on providing healthcare access

THE REVOLUTION

• The explosive growth of the Internet economy and the reform of medical treatment systems have accelerated the growing mHealth market.
• At present, the mHealth APP market is explosively growing due to the popularization of smartphones.

The smartphone revolution is under-hyped, more people have access to phones than access to running water. We've never had anything like this before since the beginning of the planet.

(Marc Andreessen)
APPLICATION CATEGORIES WITHIN THE M-HEALTH FIELD

1. Education and awareness
2. Helpline
3. Diagnostic and treatment support (telemedicine)
4. Point-of-care diagnostics
5. Communication and training for healthcare workers
6. Disease and epidemic outbreak tracking
7. Remote monitoring (treatment support and medication compliance)
8. Remote data collection

A Cluster-Randomized Trial of Blood-Pressure Reduction in Black Barbershops

Table 2. Primary and Secondary Blood-Pressure Outcomes.*

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Intervention Group (N = 132)</th>
<th>Control Group (N = 171)</th>
<th>Intervention Effect</th>
<th>P Value†</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Blood pressure</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic blood pressure — mm Hg</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At baseline</td>
<td>152.8±10.3</td>
<td>154.6±12.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>At 6 mo</td>
<td>125.8±11.0</td>
<td>145.4±15.2</td>
<td>-21.6 (-28.4 to -14.7)†</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Change</td>
<td>-27.0±13.7</td>
<td>-9.3±16.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diastolic blood pressure — mm Hg</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At baseline</td>
<td>92.2±11.5</td>
<td>89.8±11.2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>At 6 mo</td>
<td>74.7±8.3</td>
<td>85.5±12.0</td>
<td>-14.9 (-19.6 to -10.3)†</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Change</td>
<td>-17.5±11.0</td>
<td>-4.3±11.8</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Hypertension control at 6 mo — no. (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood pressure &lt;140/90 mm Hg</td>
<td>118 (89.4)</td>
<td>55 (32.2)</td>
<td>3.4 (2.5 to 4.6)¶</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Blood pressure &lt;135/85 mm Hg</td>
<td>109 (82.6)</td>
<td>32 (18.7)</td>
<td>5.5 (2.6 to 11.7)¶</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Blood pressure &lt;130/80 mm Hg</td>
<td>84 (63.6)</td>
<td>20 (11.7)</td>
<td>5.7 (2.5 to 12.8)¶</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
Table 3  Characterization of e-patients

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equipped</td>
<td>Possessing skills to manage their own condition.</td>
</tr>
<tr>
<td>Enabled</td>
<td>Make choices about self-care and finding those choices respected.</td>
</tr>
<tr>
<td>Excellent patient-care</td>
<td>Promote centre of excellence, centre of clinical trials, networks.</td>
</tr>
<tr>
<td>Engaged</td>
<td>Engaged in their own care.</td>
</tr>
<tr>
<td>Expert patients</td>
<td>Able to improve their self-rated health status; cope with generic features of chronic disease and dependence on hospital care; able to share their experience and convince other patients.</td>
</tr>
<tr>
<td>Evaluating</td>
<td>Evaluate not only the information found but also the source of that information; establishing trust in sources at an early stage (website of the trial, information by and the patient during a trial).</td>
</tr>
<tr>
<td>Equal</td>
<td>The e-patient expects to be an equal member of the team in partnership with professionals involved in their care.</td>
</tr>
</tbody>
</table>
EFFECT OF SELF-MONITORING

With Medication Self-titration - TASMIN-SR

Adherence


M-HEALTH

- Can offer continuous care, that can:
  - break the limitation of time and space,
  - reduce the cost of medical care,
  - improve the quality of medical services,
  - effectively change the status quo.

- The main contents of the continuous care for patients with hypertension are:
  - health education,
  - the patients’ compliance
  - behavior intervention,
  - BP monitoring,
  - lifestyle changing,
  - diet care,
  - psychological counseling

TELEMEDICINE

- Can reinforce and empower the physician-patient relationship, may even try to individualize it
- May help empowering hypertensive patients, influencing their attitudes and behaviors, and improving their medical condition
- Physicians can provide services to an increased number of patients
- Patients to easily and rapidly communicate to their doctors the occurrence of acute symptoms or sudden BP raises
- Can reduce patients’ stress

SMS-TEXT ADHERENCE SUPPORT (STAR)

- Single-blind, 3-arm, randomized trial (control, information-only SMS, interactive SMS)
- 1372 patients
- The information-only adherence support group members were sent messages to motivate collecting and taking medicines and to provide education about hypertension and its treatment
- The interactive group could even have a bidirectional communication with SMS

**Table 2. Mean SBP Outcomes (Including Primary Outcome)**

<table>
<thead>
<tr>
<th></th>
<th>UC</th>
<th>IO</th>
<th>IN</th>
<th>Difference in Mean Change (95% CI), * IO vs UC</th>
<th>P Value*</th>
<th>Difference in Mean Change (95% CI), * IN vs UC</th>
<th>P Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline mean SBP, mm Hg</td>
<td>135.4 (17.6)</td>
<td>135.1 (16.9)</td>
<td>135.6 (18.1)</td>
<td>...</td>
<td>...</td>
<td>...</td>
<td>...</td>
</tr>
<tr>
<td>6-mo Mean SBP, mm Hg</td>
<td>128.9 (17.1)</td>
<td>130.1 (16.6)</td>
<td>128.2 (17.5)</td>
<td>0.3 (−2.5 to 3.1)</td>
<td>0.82</td>
<td>−0.9 (−3.7 to 1.9)*</td>
<td>0.53</td>
</tr>
<tr>
<td>12-mo Mean SBP, mm Hg†</td>
<td>134.3 (17.3)</td>
<td>132.1 (16.6)</td>
<td>132.7 (17.5)</td>
<td>−2.2 (−4.4 to −0.04)</td>
<td>0.046</td>
<td>−1.6 (−3.7 to 0.62)*</td>
<td>0.16</td>
</tr>
</tbody>
</table>

There are different modalities of data collection, transmission and reporting, and by additional features such as reminding facilities for BP measurement to be performed and/or for medication intake, and automatic data reporting.

THE APPS

- Rates of smartphone ownership have increased sharply in recent years and stood at 77% in 2016, they are becoming an integral part of people’s lives.
- In 2016, approximately 100,000 new health-related apps were published and the health app download rates were estimated 3.2 billion.
- By 2020 around 60% (4.6 billion people) of the global population will have a mobile subscription.
- The main target areas of app developers are chronic diseases such as hypertension and diabetes.

- Lack of involvement from medical experts in the process of app development
- Personal data
The most common application of mHealth is to educate patients about prevention and self-management of HTN while receiving treatment support from healthcare providers through this technology.

Mobile devices could be used to capture, store, and transfer health information of patients to their providers.

The types of interventions can vary. For example, mild interventions can simply be suggestions or reminders through text messages sent to the patients and can be handled by a nurse practitioner while a higher order intervention could be medical advice including new medications or dosage changes and can be handled by a physician.
MAIN SERVICES PROVIDED BY HYPERTENSION SMARTPHONE APPS

- Logbooks: 10
- Notifications: 10
- Reminders: 20
- Medication adherence: 22
- Healthcare professional assistance: 4
- Alternative treatments: 4
- Diet: 8
- General information: 33
- Hypertension education: 37
- Salt intake: 3
- Caloric intake: 5
- Body weight: 27
- Pulse rate: 62
- Blood pressure: 69
- Tracking function: 72

POLICY AND REGULATORY INITIATIVES ON M-HEALTH

Bush Administration
- April: Health Information Technology Initiative
- May: the Office of the National Coordinator for Health Information Technology (ONC) in United States Department of Health and Human Services
  - Health and Human Services referred to mHealth as the biggest technology breakthrough of our time
  - WHO said mHealth is new horizons for health through mobile technologies
    - FDA was given approval to go forward with regulatory work on medical apps
    - FCC approved its mobile body area network (MBAN)

- 2004
- 2011
- 2012
- 2013
- 2014
- 2015
- 2016
- 2017
- FDA determined first digital medicine
- FDA released guidance on mobile medical apps
- The 21st Century Cures Act clarified FDA's regulation of medical software
  - FDA released additional guidance on mobile device data systems (MDDS)
  - FDA announced to create Digital Health Unit
  - FDA approved first digital medicine
<table>
<thead>
<tr>
<th>Variable</th>
<th>Unadjusted models</th>
<th>Adjusted models(^a)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Odds ratio (95% CI)</td>
<td>P value</td>
<td>Odds ratio (95% CI)</td>
</tr>
<tr>
<td><strong>Chronic conditions</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No chronic condition</td>
<td>Reference</td>
<td></td>
<td>Reference</td>
</tr>
<tr>
<td>Hypertension</td>
<td>0.34 (0.21-0.53)</td>
<td>&lt;.001</td>
<td>0.74 (0.45-1.22)</td>
</tr>
<tr>
<td>Obesity</td>
<td>1.18 (0.72-1.94)</td>
<td>.51</td>
<td>1.63 (0.96-2.77)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>0.61 (0.36-1.04)</td>
<td>.07</td>
<td>1.24 (0.69-2.24)</td>
</tr>
<tr>
<td>Depression</td>
<td>0.72 (0.52-1.00)</td>
<td>.05</td>
<td>0.91 (0.64-1.28)</td>
</tr>
<tr>
<td>High cholesterol</td>
<td>0.46 (0.35-0.59)</td>
<td>&lt;.001</td>
<td>1.00 (0.73-1.37)</td>
</tr>
<tr>
<td><strong>Self-reported health</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Poor health</td>
<td>Reference</td>
<td></td>
<td>Reference</td>
</tr>
<tr>
<td>Fair health</td>
<td>1.07 (0.69-1.66)</td>
<td>.76</td>
<td>1.30 (0.82-2.07)</td>
</tr>
<tr>
<td>Good health</td>
<td>1.29 (0.86-1.94)</td>
<td>.23</td>
<td>1.55 (1.00-2.40)</td>
</tr>
<tr>
<td>Very good health</td>
<td>3.28 (2.12-5.06)</td>
<td>.000</td>
<td>3.80 (2.38-6.09)</td>
</tr>
<tr>
<td>Excellent health</td>
<td>5.36 (3.14-9.14)</td>
<td>.000</td>
<td>4.77 (2.70-8.42)</td>
</tr>
<tr>
<td><strong>Physical activity</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>Reference</td>
<td></td>
<td>Reference</td>
</tr>
<tr>
<td>1 day per week</td>
<td>3.08 (2.05-4.64)</td>
<td>.000</td>
<td>2.47 (1.60-3.83)</td>
</tr>
<tr>
<td>2 days per week</td>
<td>5.38 (3.78-7.66)</td>
<td>.000</td>
<td>4.77 (3.27-6.94)</td>
</tr>
<tr>
<td>3-4 days per week</td>
<td>6.15 (4.43-8.54)</td>
<td>.000</td>
<td>5.00 (3.52-7.10)</td>
</tr>
<tr>
<td>5-7 days per week</td>
<td>5.13 (3.53-7.45)</td>
<td>.000</td>
<td>4.64 (3.11-6.92)</td>
</tr>
</tbody>
</table>

LIFE STYLE INTERVENTIONS

- The programme included in-app human coaching with bi-weekly phone calls, meal logging, blood pressure tracking and educational material.
- Dietary elements of the programme were based on the DASH diet.
- 6 months duration.

<table>
<thead>
<tr>
<th>Completers</th>
<th>Weight change (kg)</th>
<th>BMI change (kg m⁻²)</th>
<th>Diastolic blood pressure change (mm Hg)</th>
<th>Systolic blood pressure change (mm Hg)</th>
<th>Hypertension category change</th>
<th>DBP change 1st-2nd curriculum half</th>
<th>SBP change 1st-2nd curriculum half</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>40</td>
<td>0.63</td>
<td>-3.73 ± 4.01</td>
<td>-2.72</td>
<td>-5.01</td>
<td>-2.44</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td></td>
<td>40</td>
<td>0.22</td>
<td>-1.42 ± 1.38</td>
<td>-1.01</td>
<td>-1.86</td>
<td>-0.98</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td></td>
<td>40</td>
<td>1.77</td>
<td>-4.13 ± 11.21</td>
<td>-3.00</td>
<td>-7.71</td>
<td>-0.54</td>
<td>0.03</td>
</tr>
<tr>
<td></td>
<td>40</td>
<td>1.99</td>
<td>-7.75 ± 12.56</td>
<td>-9.00</td>
<td>-11.77</td>
<td>-3.73</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td></td>
<td>40</td>
<td>0.10</td>
<td>-0.58 ± 0.64</td>
<td>-1.00</td>
<td>-0.78</td>
<td>-0.37</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td></td>
<td>27</td>
<td>0.89</td>
<td>-0.78 ± 4.64</td>
<td>-1.00</td>
<td>-2.61</td>
<td>1.06</td>
<td>0.39</td>
</tr>
<tr>
<td></td>
<td>27</td>
<td>1.95</td>
<td>-3.26 ± 10.14</td>
<td>-2.00</td>
<td>-7.27</td>
<td>0.75</td>
<td>0.11</td>
</tr>
</tbody>
</table>

Table 3. Blood pressure outcomes at 24 weeks

<table>
<thead>
<tr>
<th>Blood pressure</th>
<th>N</th>
<th>Starters</th>
<th>N</th>
<th>Completers</th>
</tr>
</thead>
<tbody>
<tr>
<td>No change</td>
<td>21</td>
<td>42%</td>
<td>17</td>
<td>43%</td>
</tr>
<tr>
<td>Reduction</td>
<td>25</td>
<td>50%</td>
<td>22</td>
<td>55%</td>
</tr>
<tr>
<td>Increase</td>
<td>4</td>
<td>8%</td>
<td>1</td>
<td>3%</td>
</tr>
</tbody>
</table>

Table 4. Percent weight loss by completion status and percentage category

<table>
<thead>
<tr>
<th></th>
<th>Starters</th>
<th>Completers</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Percentage</td>
</tr>
<tr>
<td>0</td>
<td>10</td>
<td>20%</td>
</tr>
<tr>
<td>0 to &lt; 3%</td>
<td>13</td>
<td>26%</td>
</tr>
<tr>
<td>3 to &lt; 5%</td>
<td>10</td>
<td>20%</td>
</tr>
<tr>
<td>5 to &lt; 7%</td>
<td>6</td>
<td>12%</td>
</tr>
<tr>
<td>7 to &lt; 10%</td>
<td>9</td>
<td>18%</td>
</tr>
<tr>
<td>≥ 10%</td>
<td>2</td>
<td>4%</td>
</tr>
<tr>
<td>Total % greater than 5%</td>
<td>34%</td>
<td>41%</td>
</tr>
</tbody>
</table>
BP TELEMONITORING WITH INTERVENTION

- 450 adults with uncontrolled BP
- 8 clinics were randomized to provide usual care to their patients (n = 222) and 8 were randomized to provide the telemonitoring intervention (n = 228).
- Intervention patients received home BP telemonitors and transmitted BP data to pharmacists who adjusted antihypertensive therapy accordingly with telephone contact
- Duration of intervention 12 months

TASMINH4

- 1182 participants were randomly assigned (1:1:1) to:
  - the self-monitoring group
  - the telemonitoring group
  - the usual care group

![Table of blood pressure data](image)

SELF-MONITORING ± INTERVENTION

Besides BP...
M-HEALTH PROS AND CONS

Pros
- Convenient and personalized care for patients
- Higher accuracy due to the absence of white-coat syndrome or masked hypertension
- Reduced office visits and travel cost for patients
- Better compliance and adherence to therapy through patient empowerment and engagement (reminders and messages)
- Easier and more efficient information sharing and coordination among caregivers and patients
- Facilitates prompt intervention by providers
- Increase in specialist efficiency through nurse-initiated or automated triage
- Possible direct and indirect cost reduction
- Enables remote monitoring of difficult-to-reach patients

Cons
- Training required for less tech-savvy patients
- Possible inaccuracy in the uploaded data by patients (patients may be subjective and selective in logging data or upload erroneous data)
- Data does not come from a medical device (reliability concern)
- Less standardized diagnostic criteria may increase the risk of self-medication
- No proper regulation and validation of the process or the technology
- Data privacy issues and HIPAA\(^1\) concerns
- Potential integration issues with EHR\(^2\) resulting in inefficiency
- Possible significant costs to maintain and update the application
- Time intensive for providers (to continuously keep track of information uploaded by patients)

\(^1\)Health Insurance Portability and Accountability Act
\(^2\)Electronic Health Records
There is also evidence that patient self-monitoring may have a beneficial effect on medication adherence and BP control, especially when combined with education and counselling. Telemonitoring and smartphone applications may offer additional advantages, such as an aid to memory to make BP measurements, and as a convenient way to store and review BP data in a digital diary and transmit them. We do not recommend the use of apps as a cuff-independent means of measuring BP.

Recent data suggest that adherence to treatment may also be improved with the use of telemetry for transmission of recorded home values, maintaining contact between patients and physicians, and studies are ongoing.

<table>
<thead>
<tr>
<th>COR</th>
<th>LOE</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ila</td>
<td>A</td>
<td>1. Telehealth strategies can be useful adjuncts to interventions shown to reduce BP for adults with hypertension.</td>
</tr>
</tbody>
</table>
SMARTPHONE APPLICATION FOR BP CONTROL

Allows to organize send the stored BP and heart rate values into a dedicated website and later controlled by physician, has a reminder for the pill intake and gives information about BP and its frequent complication.
VALIDATION OF A NOVEL CUFF-LESS BP MONITORING DEVICE


Big data refers to the enormous amount of structured as well as unstructured data, which helps organizations to improve their decision making processes.
Technology is not the panacea for the healthcare industry... but it is part of the solution!