Digital Health and Clinical Practice Guidelines

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Advanced mHealth (e.g. biosensors)
Digital Health and Clinical Practice Guidelines

(1) Education
- ESC Clinical Practice Guidelines Apps
- Integration of ESC Guidelines into EHR-based Decision Tools

(2) Evaluation of Evidence for Digital Health in CVD Prevention and Management
- Mobile Health
- AI-based algorithms
- Integration of genetics
Age and Gender of ESC GL App Users 2018

- **35 & under**: 9,045 females, 1,533 males, 14 unknown gender
- **36-39**: 1,834 females, 1,533 males, 17 unknown gender
- **40-45**: 4,013 females, 1,533 males, 14 unknown gender
- **46-50**: 2,177 females, 797 males, 7 unknown gender
- **51-55**: 1,901 females, 546 males, 5 unknown gender
- **56-60**: 1,618 females, 358 males, 5 unknown gender
- **Over 60**: 1,995 females, 266 males, 4 unknown gender
- **Unknown age**: 4,017 females, 137 males, 277 unknown gender
Simplicity

- Easier and rapid access to flow-charts and tables
- Better navigation and full table view
ESC Guidelines into the digital health solutions

ESC guidelines based decision support tools can be implemented in electronic medical reports.
Digital Health – Education
ESC Guidelines – Digital applications

- ESC guidelines Apps
- ESC guidelines-based decision support
Digital Health and Clinical Practice Guidelines

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Digital Health recommendations in Clinical Practice Guidelines

2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure

The Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC)

| Monitoring of pulmonary artery pressures using a wireless implantable haemodynamic monitoring system (CardioMems) may be considered in symptomatic patients with HF with previous HF hospitalization in order to reduce the risk of recurrent HF hospitalization. | IIb | B | 628, 629 |
| Multiparameter monitoring based on ICD (IN-TIME approach) may be considered in symptomatic patients with HFrEF (LVEF ≤35%) in order to improve clinical outcomes. | IIb | B | 630 |

Careful development of algorhythms for remote monitoring important.
mHealth (e.g. biosensors)
Big data (e.g. genetics)
Artificial Intelligence
Apps, Wearables
Sensors and Biomedical Data Acquisition

Example: Apple Watch and the Detection of Atrial Fibrillation

HEARTLINE Study:

• Plans to enroll up to 150,000 Americans 65 and older, randomized to receive either an Apple Watch coupled with HEARTLINE app, or no watch (ECG app on the latest Series 4 Apple Watch)

• Primary outcome: Clinically confirmed diagnosis rate of AF?
• Secondary outcome: MACE (stroke, MI, all-cause death)
Novel approaches for detection of Atrial Fibrillation

- Dedicated ECG screening devices
- Long-term ECG monitoring
- Non-ECG technologies
Digital technology to support self-management in patients with coronary disease

• Comments on digital health-based self-managing systems for patients with coronary disease
  
  • E.g. Ischemia/ACS detection
    • AngelMed (FDA approved for patients with recent ACS)
    • RELF algorhythm
    • ESC guidelines recommendations?
ESC will take a leadership role in convergence of digital health and artificial intelligence (AI) in CVD

Comment

Governing health futures 2030: growing up in a digital world—a joint *The Lancet* and *Financial Times* Commission

*Lancet*. 2019 Sep 20 [Epub ahead of print]
mHealth (e.g. biosensors)

Big data (e.g. genetics)

Artificial Intelligence

Apps, Wearables
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An artificial intelligence-enabled ECG algorithm for the identification of patients with atrial fibrillation during sinus rhythm: a retrospective analysis of outcome prediction

Zachi J Attia*, Peter A Noseworthy*, Francisco Lopez-Jimenez, Samuel J Asirvatham, Abhishek J Deshmukh, Bernard J Gersh, Rickey E Carter, Xiaoxi Yao, Alejandro A Rabinstein, Brad J Erickson, Suraj Kapa, Paul A Friedman

650 000 ECGs from a cohort of 180 922 patients aged >18 years

Lancet 2019; 394: 861–67; Published Online August 1, 2019
An artificial intelligence-enabled ECG algorithm for the identification of patients with atrial fibrillation during sinus rhythm: a retrospective analysis of outcome prediction

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<table>
<thead>
<tr>
<th></th>
<th>AUC</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>F1 score</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Main analysis</td>
<td>0.87 (0.86-0.88)</td>
<td>79.0% (77.5-80.4)</td>
<td>79.5% (79.0-79.9)</td>
<td>39.2% (38.1-40.3)</td>
<td>79.4% (79.0-79.9)</td>
</tr>
<tr>
<td>Secondary analysis</td>
<td>0.90 (0.90-0.91)</td>
<td>82.3% (80.9-83.6)</td>
<td>83.4% (83.0-83.8)</td>
<td>45.4% (44.2-46.5)</td>
<td>83.3% (83.0-83.7)</td>
</tr>
</tbody>
</table>

Data in parentheses are 95% CIs. In the main analysis, only the score of the first normal sinus rhythm ECG in the window of interest was used. In the secondary analysis, the highest score for all ECGs done in the first month of the window of interest was used. AUC=area under the curve. ECG=electrocardiograph.

Table: Model performance
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FUTURE: Personalised Maintenance of CV Health
Genomics, Biomarkers, Advanced Phenotyping (Imaging, Digital) – Integrated by AI-based algorithms

GENOMICS

ADVANCED DEEP PHENOTYPING
(eg Imaging of Subclinical Disease)

CLINICAL DATA
BIOMARKERS, WEARABLES

Digital Precision Medicine:
Personalised Maintenance of CV Health/Management of CV Disease by Targeting Causal Pathophysiological Mechanisms of Disease Progression

Novel Artificial Intelligence-Based Algorhythms

Adapted and modified from:
Leistner D, Landmesser U. Eur Heart J 2019; 40: 9-12
ESC-CPG
Methodology Task Force

Started in 2018, will provide a document for methodology for ESC Clinical Practice Guidelines
Topics of Methodology Consensus Document

Levels of Evidence/Grading

➢ Therapeutic decisions
  ➢ Meta-analyses vs single RCTs
  ➢ Role of observational studies

➢ Prognostic information
  ➢ RCTs not required

➢ Diagnostic tools
  ➢ When are observational studies enough?
  ➢ When are RCTs required?
Levels of Evidence/Grading for Therapeutic Decisions

➢ Meta-analyses
  ➢ Based on systematic review
  ➢ Size of 2 largest trials (patients, events)
  ➢ Funnel plot
  ➢ Heterogeneity between trials: $I^2$, $\tau^2$, $\tau$
  ➢ Effect estimate (HR, RR etc.)
  ➢ 95% confidence interval or p-value as evidence against null hypothesis (p<0.005)
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