Télé médecine en BPCO : big promises, few details?

J. BOURBEAU
McGill University, Montréal
<table>
<thead>
<tr>
<th></th>
<th>Sujet</th>
<th>Décret</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Consultation fees</td>
<td>none</td>
</tr>
<tr>
<td>2</td>
<td>Stock ownership/profit</td>
<td>none</td>
</tr>
<tr>
<td>3</td>
<td>Patent fees</td>
<td>none</td>
</tr>
</tbody>
</table>
| 4 | Remuneration for lecture                     | Private: AZ, BI, Grifols, Novartis  
                             Public: UDM, RQESR, CTS, Chest, Respiplus |
| 5 | Manuscript fees                              | none     |
| 6 | Trust research/joint research funds           | Private: Aerocrine, AZ, BI, GSK, Novartis  
                             Public: CIHR, CRRN, FRQS, RI MUHC |
| 7 | Affiliation with Endowed Department           | none     |
| 8 | Other remuneration such as gifts              | none     |
Agenda

1. Définition(s)
2. Les études
   - Les évidences
   - Les recommendations
   - Les opportunités
3. L’ étude COMET: le Canada visite l’Europe
4. 20 ans plus tard
Définitions

<table>
<thead>
<tr>
<th>Telemedicine</th>
<th>Distribution of health services in conditions where distance is a critical factor, by healthcare providers that use ICT to exchange information useful for diagnosis at distance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Telecommunications</td>
<td>Use of cable connections, radio, optical means or other electromagnetic channels to transmit or receive signals, such as voice, data or video communications</td>
</tr>
<tr>
<td>Telematics</td>
<td>Use of telecommunications to permit computers to transfer programs and data</td>
</tr>
<tr>
<td>Teleconsultation</td>
<td>Second opinion on demand between patient/family and staff or among health operators; opinions, advice provided at distance between two or more parties separated geographically</td>
</tr>
<tr>
<td>Telemonitoring</td>
<td>Digital/broadband/satellite/wireless or Bluetooth transmission of physiological and other noninvasive data (i.e. biological storage data transfer)</td>
</tr>
<tr>
<td>Decision support systems</td>
<td>According to a sentinel value, an alert starts for health personnel, who call patient</td>
</tr>
<tr>
<td>Remote diagnosis</td>
<td>Identifying a disease by the assessment of the data transmitted to the receiving party through instrumentation monitoring a patient away from the clinic</td>
</tr>
<tr>
<td>Tele-evaluation</td>
<td>On-demand data transfer to use as biological outcome measures</td>
</tr>
<tr>
<td>Telecare</td>
<td>Network of health and social services in a specific area; in case of emergency, patient calls medical personnel, emergency call service or members of family</td>
</tr>
<tr>
<td>Telerehabilitation</td>
<td>Allows reception of homecare and guidance on the process of rehabilitation through connections for point-to-point video conferencing between a central control unit and a patient at home</td>
</tr>
<tr>
<td>Telecoaching</td>
<td>Direct reinforcement or recorded messages/communications to improve adherence</td>
</tr>
<tr>
<td>Teleconference, audio</td>
<td>Electronic two-way voice communication between two or more people located in different places</td>
</tr>
</tbody>
</table>

American Telemedicine Association defines it as “the use of medical information exchanged from one site to another via electronic communications to improve a patient’s clinical health status.”

C'est un exercice de la médecine par le biais des télécommunications et des technologies qui permettent les prestations de santé à distance et l'échange de l'information médicale s'y rapportant.
Cliquez et modifiez le titre

Télémédecine en BPCO

Cochrane review de 10 RCTs
Aucune amélioration de la qualité de vie
Pourrait réduire les risques de visites en urgence et d’hospitalisations.¹

Méta-analyse plus récentes de 18 RCTs n’a pas démontré d’amélioration de la qualité de vie.²

Télémedicine en BPCO

13 RCTs

Echantillon total de patients: 40-256

Technologies:
• Tel (quelques fois avec dispositifs médicaux) : 9
• Video conf: 1
• Dispositifs médicaux connectés par internet: 3

Mesures: questionnaires, VEMs, Saturation, TA

Resultats:
• Diminutions des admissions: 5
• Aucun effet: 6
• Détérioration des admissions: 2

Pedone C and Lelli D, Pneumonol Alego Pol 2015;83:476-484.
Il y a un manque d'études de qualité et celles existantes sont:
• petites études,
• courte durée, et
• hétérogénéité des interventions et du traitement usuel de comparaison.

Les méta-analyses ont produit des résultats contradictoires.
Telemonitoring comprised the following elements:

1. electronic transfer of self-report or biometric data (eg, oxygen saturation, pulse rate, BP) over a distance;
2. use of a device located in the patient’s home or on his or her person (mobile device); and
3. personalized feedback from a health-care professional who exercises his or her skills and judgment in the provision of tailored advice to the patient or automated feedback based on a predetermined algorithm.
Substantial variability in the telemonitoring interventions and equipment used, which included recording and electronic transmission of:

- vital signs (spirometry, pulse oximetry, heart rate, and BP);
- technology platform for delivery of education and transmission of pedometer results;
- hand-held monitor, self-reported symptoms, and manually entered temperature and oximetry;
- sensor-containing wrist-bands for heart rate, physical activity, near body temperature, and galvanic skin response; commercial oximeter and cell phone coupled with a wristband;
- self-report data (EXACT-PRO questionnaire) transmitted through cell phones; and
- automated alert calls based on winter weather conditions.

Criner, Bourbeau, Diekemper et al. Chest 2015; 894-942
11. We suggest that telemonitoring compared to usual care does not prevent acute exacerbations of COPD, as assessed by decreases in emergency room visits, exacerbations or hospitalizations over a 12-month period (Grade 2C)

Underlying values and preferences:
• There is insufficient evidence at this time to support the contention that telemonitoring prevents COPD exacerbations
Quoi attendre de la Télémédecine en BPCO ?

Opportunité de combler les écarts pour mieux livrer et améliorer l’autogestion

1-Améliorer l’autogestion en la rendant disponible chez le patient dans son environnement de vie, et assurer le transfert d’info au moment le plus opportun: renforcer le lien entre info et action (strengthens behavior change).

2- Permettre au patient
• de communiquer avec son case manager et recevoir le soutien nécessaire;
• de recevoir l’éducation pertinente à sa condition.

3-Permettre au case manager de faire un monitoring continue et soutien d’un plus grand nombre de patients et ainsi réserver les visites en personne aux patients qui en ont le plus de besoin.
COPD patient Management European Trial (COMET)”, initiated in 2006

COMET: an investigational home-based COPD disease management programme

- To achieve the optimal daily life and health status for the individual patient
- To maintain independence and integration in the community

Will adopting positive home-behaviours improve the lives of patient with COPD?

**COMET Global Objectives**

- **A home-based COPD disease-management programme**
  - WILL HELP
  - Patients with severe COPD learn and adopt the behaviours needed to cope with their disease
  - AND CONSEQUENTLY
  - Among important outcomes, it will result in a reduction in hospitalisations

COPD, chronic obstructive pulmonary disease.

Disease management programme based on ‘Living Well with COPD” and telemedicine platform

Components of the COMET trial

- **Self-management program:** involve patient self-management education LWWCOPD & coaching by case managers

- **Phone service with e-platform:**
  - weekly/daily reporting by patient with automatic analysis of clinical symptoms
  - worsening triggers an alarm, standardized nurse intervention & transmission to the referent hospital physician for medical decision

COMET: control group

Usual management (control group)

Received the usual or routine COPD care and patient follow-up practices used at each investigational centre.

Site-specific usual management practices
  • centre-specific COPD educational booklets or programme information.

were collected at the beginning and end of the patient inclusion period.
COMET: Quality control / Assurance

Quality Control / Assurance

Standardization of the program/content
- self-management program Living Well with COPD (LWWCOPD)

Case managers
- experienced in taking care of home-based chronic patients;
- initial four-day training (+specific training MI);
- access given to ‘reference guides’ describing the objectives, interventions, suggested questions, expected results and resources;
- trainings at each country level during the study for new comers, program refreshing and experience sharing.

Monthly telephone contacts
- between the case managers and a pneumologist from the COMET study coordination center, in each country separately
COMET was focused on patients with severe COPD treated at home\textsuperscript{1}

Main eligibility criteria

- COPD stage III or IV (GOLD)
- \textgeq 1 exacerbation leading to hospitalisation in previous 12 months
- Current or ex-smoker (history: \textgeq 10 pack-years)
- Limited probability of survival (<6 months)
- Permanently living in a nursing home
- No insurance coverage

Main exclusion criteria

COMET is an international, randomised, home-based trial

Study design\(^1,2\)

<table>
<thead>
<tr>
<th>RANDONMINATION</th>
<th>Disease management group</th>
<th>Usual management group</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>12</td>
<td>24</td>
</tr>
</tbody>
</table>

Run-in period (5 weeks) Follow up 12 to 24 months

First patient in | Last patient out
Sep 2010 | 33 centres Target: 306 patients (153 per group) | Mar 2015

France 12 centres
Germany 8 centres
Spain 7 centres
Italy 6 centres

Will adopting positive home-behaviours improve the lives of patients with COPD?

**Primary objective**

To compare the effect of a multicomponent, home-based COPD self-management programme versus usual care on *all-causes hospital days* in patients with severe COPD.

**Primary:** all causes, acute care wards and subsequent nursing facilities, ITT

**Supportive:**
- Primary, per protocol (PP)
- All causes, acute care wards only, ITT and PP
- For AECOPD, ITT and PP
Patient flow

Patients randomised
N=345

Disease management
N=172
Patient withdrawals, n=10
Investigator withdrawals, n=3
Lost to follow-up, n=2

Entered follow-up
N=157
Patient withdrawals, n=11
Investigator withdrawals, n=4
Lost to follow-up, n=2
Patient deaths, n=3

Major protocol deviations, n=23
Eligibility criteria (8)
Follow-up < 3 months (2)
Received < 26% training (15)
Server not activated (2)

Completed study
N=137
Per-protocol
N=134
Mean follow-up 12.2 ± 3.5 mo

Run-in period
(5 wk)

Usual management
N=173
Patient withdrawals, n=8
Investigator withdrawals, n=2
Lost to follow-up, n=1

Entered follow-up
N=162
Patient withdrawals, n=6
Investigator withdrawals, n=3
Lost to follow-up, n=2
Patient deaths, n=23

Major protocol deviations, n=8
Eligibility criteria (9)

Completed study
N=128
Per-protocol
N=154
Mean follow-up 12.3 ± 3.3 mo

Intention-to-treat
N=319
Follow-up period
(12–24 mo)

Completed study
N=265
Per-protocol
N=288
Mean follow-up 12.2 ± 3.4 mo
Primary efficacy endpoint: number of hospital days, all-cause, acute care + subsequent nursing facilities

In all countries, in the ITT population (n=319)

17.4 (SD35.4) days

-5.32 days
[95% CI -13.69; 3.05]
not statistically significant
p=0.161
(Wilcoxon’s test)

22.6 (SD41.8) days
Primary efficacy endpoint: EVC assessment

In all countries, in the ITT population (n=319)

<table>
<thead>
<tr>
<th>Primary Causes for Hospital Admissions According to EVC Assessments</th>
<th>Disease Management (n=157)</th>
<th>Usual Management (n=162)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory</td>
<td>68 (43.3 %)</td>
<td>75 (46.3%)</td>
</tr>
<tr>
<td>Other Medical Reason</td>
<td>15 (9.6%)</td>
<td>17 (10.5%)</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>6 (3.8%)</td>
<td>7 (4.3%)</td>
</tr>
<tr>
<td>Surgical</td>
<td>2 (1.3%)</td>
<td>4 (2.5%)</td>
</tr>
<tr>
<td>Cancer</td>
<td>1 (0.6%)</td>
<td>2 (1.2%)</td>
</tr>
<tr>
<td>Not Assessable</td>
<td>0 (0.0%)</td>
<td>1 (0.6%)</td>
</tr>
</tbody>
</table>

All-causes, acute care and subsequent nursing facilities yearly number of hospital days

15.5 (SD32.9) days (DM) vs 20.8 (SD38.8) days (UM)

not statistically significant
(p=0.150, Wilcoxon’s test)

In the Per Protocol population (n=288): 13.2 (SD28.3) days (DM) vs 21.2 (SD39.5) days (UM)
(p=0.106, Wilcoxon’s test)

ITT, intention-to-treat.
Categories were exclusive (e.g., lung cancer surgery was categorised in surgery but was not included in cancer and respiratory).
Other medical reason includes anxiety, asthenia, diarrhoea, fall, thermal burn, syncope.
### Secondary efficacy endpoint: Fewer all-cause Acute Care hospital days

#### In all countries, supportive and secondary analyses of hospitalisation endpoint

<table>
<thead>
<tr>
<th>Disease Management</th>
<th>Usual Management</th>
<th>Difference in adjusted means [95% CI]²</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Disease Management</strong></td>
<td><strong>Usual Management</strong></td>
<td><strong>Difference in adjusted means [95% CI]²</strong></td>
<td><strong>P</strong></td>
</tr>
<tr>
<td>Intent-to-treat hospitalization days&lt;sup&gt;b&lt;/sup&gt;</td>
<td>N=157</td>
<td>N=162</td>
<td></td>
</tr>
<tr>
<td>Primary endpoint (all-cause, acute care/nursing facilities)</td>
<td>17.4 ± 35.4</td>
<td>22.6 ± 41.8</td>
<td>-5.3 [-13.7; 3.1]</td>
</tr>
<tr>
<td>All-cause, acute care wards</td>
<td>14.1 ± 28.7</td>
<td>20.9 ± 40.5</td>
<td>-6.9 [-14.5; 0.7]</td>
</tr>
<tr>
<td>For AECOPD, acute care/nursing</td>
<td>7.8 ± 16.4</td>
<td>9.1 ± 20.8</td>
<td>-1.5 [-5.5; 2.5]</td>
</tr>
<tr>
<td>HOT/HMV patients (n=243)</td>
<td>20.1 ± 38.7</td>
<td>26.0 ± 44.8</td>
<td>-5.7 [-14.2; 2.7]</td>
</tr>
<tr>
<td><strong>Per protocol hospitalization days&lt;sup&gt;b&lt;/sup&gt;</strong></td>
<td><strong>N=134</strong></td>
<td><strong>N=154</strong></td>
<td><strong>-8.0 [-16.6; 0.6]</strong></td>
</tr>
<tr>
<td>Primary endpoint (all-cause, acute care/nursing facilities)</td>
<td>15.1 ± 31.6</td>
<td>23.0 ± 42.6</td>
<td></td>
</tr>
<tr>
<td>All-cause, acute care wards</td>
<td>13.1 ± 28.2</td>
<td>21.1 ± 41.3</td>
<td><strong>-8.3 [-16.4; -0.1]</strong></td>
</tr>
<tr>
<td>For AECOPD, acute care/nursing</td>
<td>8.3 ± 17.5</td>
<td>9.1 ± 21.2</td>
<td>-1.4 [-5.7; 3.0]</td>
</tr>
<tr>
<td>HOT/HMV patients (n=215)</td>
<td>17.1 ± 34.5</td>
<td>26.7 ± 46.0</td>
<td>-8.3 [-17.1; 0.4]</td>
</tr>
</tbody>
</table>

CI, confidence interval.

---

²Confidence interval.
Safety endpoint: Significantly fewer deaths in the DM arm.

In all countries, all-causes deaths during the follow-up period:

- Cause of death was respiratory in 62% of cases and occurred in hospital settings.
- Prognostic factors for death were baseline BODE index, and the total number of days of hospitalisation after selection whatever their reason.

1 patient died prior to randomisation from sudden death (unknown cause).

BODE, Body mass index, degree of airflow Obstruction, Dyspnoea and Exercise capacity; DM, disease management; UM, usual management.
Other secondary efficacy endpoints: Favorable impact on chronic COPD condition

Significant cessation of smoking:
9/34 (DM) vs 2/34 (UM) current smokers at baseline
p=0.021

Significant reduction in the BODE index at 1 year:
difference in adjusted means
−0.5 [95% CI: −0.9; −0.1], p=0.010

BODE, Body mass index, degree of airflow Obstruction, Dyspnoea and Exercise capacity; improvement or worsening is change ≥1 DM, disease management; UM, usual management.
COMET: program adherence

• Two-thirds to 90% of the DM group patients received at least 80% of the planned number of coaching sessions;

• 80% compliant with the weekly phone calls to transmit health status, and most acquired disease management skills.
Take-home messages

• COMET showed that it is possible to improve the management of patients with severe COPD and this could have impact on patient outcome

• More specifically: COMET provides key learnings in home-management of severe COPD patients with self-management intervention and the support of health care professional (case manager)
  – All-cause hospital days were decreased but not statistically significant (ITT)
  – All-cause Acute Care hospital days were decreased and statistically significant (PP)
  – Deaths were significantly less
  – Self-management skills, smoking habits and BODE index were favourably modified

• Novel aspects of the disease management intervention included an e-health platform for reporting frequent health status updates, rapid intervention when necessary, and oxygen therapy monitoring
Télémédecine... 20 ans plus tard

Surprise et déception!

Cependant:
• Beaucoup d’études ont rapporté des résultats positifs dans les essais cliniques randomisés
• Les effets bénéfiques sont probablement dus à l’attention donné, éducation thérapeutique et case manager dans l’intervention « télémédecine »
• Peu d’étude économique

Future work:
• Il est nécessaire que les études futures distinguent l’apport réel de la télémécine
• Opportunité de combler les écarts pour mieux livrer et améliorer l’autogestion

Wootton Journal of Telemedicine and Telecare 2012; 18: 211–220