Protocol No: P2022-02
IDRCB N°: 2022-A00488-35

Validation by three-dimensional actimetry measurements of a predictive algorithm for excessive inactivity in COPD patients

Multicenter study

VERSION N°3 OF 30/09/2022

INFORMATION SHEET

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Last Name: AGUILANIU

Date of birth: 05.01.1954

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Telephone: +33680984146

E-mail: b.aguilaniu@gmail.com

Title: Associate Professor of Pulmonology

Duties: Pulmonologist (Private Practice)

Name of the Head of Department or Laboratory: NA

Project title: Validation of a predictive algorithm for excessive inactivity in COPD patients using three-dimensional actimetry measurements

Project sites: Pulmonologists (University Hospitals, General Hospitals, Private Hospitals) in Auvergne Rhône-Alpes and Alpes Maritimes, France

Schedule:

- Start of inclusions: January 2023
- End of inclusions: July 2023
- End of the study: December 2023

Name and address of the structure that carries the research project:

aCCPP, Association pour la Complémentarité des Connaissances et des Pratiques en Pneumologie, represented by its President (Pr Christophe Pison) and Vice-President (Dr Eric Kelkel), 19 avenue Marcelin Berthelot, 38 100 Grenoble – FRANCE

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CLASSIFICATION OF THE STUDY OR RESEARCH PROJECT: COPD (other respiratory diseases / non-transmissible chronic respiratory diseases)

PROTOCOL SIGNATURE PAGE

Study title: Validation of a predictive algorithm for excessive inactivity in COPD patients using three-dimensional actimetry measurements

Protocol version and date: version n°3 of 30/09/2022

Internal number: P2022-02

This protocol has been read and approved on the date noted below.

The parties agree to conduct the research in accordance with the protocol and the legislative and regulatory provisions in force.

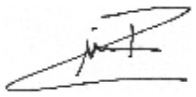
Sponsor's representative: aCCPP — **Date**: 30/09/2022

Mr. Christophe Pison — **Signature**

President

19 avenue Marcelin Berthelot

38 100 GRENOBLE



Mrs Anne Rigal — **Date**: 30/09/2022

Project Manager — **Signature**

19 avenue Marcelin Berthelot

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Principal Investigator/Coordinator — **Date**: 30/09/2022

Pr. Bernard Aguilaniu — **Signature**

Pulmonologist (Private Practice)

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TABLE OF CONTENTS

SUMMARY

Project title: Validation of a predictive algorithm for excessive inactivity in COPD patients using three-dimensional actimetry measurements.

Name of the candidate: Pr. Bernard Aguilaniu for the aCCPP

Summary:

It has been shown that COPD patients have a significantly decreased daily physical activity (DPA) compared to matched subjects. Moreover, the severity of inactivity is correlated with several prognostic indices such as the frequency of exacerbations, quality of life and mortality. These findings lead to the recommendation, with a level of evidence A, of DPA in the context of medically supervised respiratory rehabilitation programs and/or by encouraging patients to participate in programs promoting physical activity.

However, despite the established benefits, it is estimated that this rehabilitative management actually involves only 10% of the patients who should benefit from it. Among the various causes of this situation, the underestimation of excessive inactivity (EI) by pulmonologists is one of the causes of this care deficit.

Currently, only actimetry can accurately assess the patient's level of physical activity.

To alert pulmonologists to this excessive situation justifying priority care, without resorting to actimetry, we developed a Machine Learning Algorithm (MLA) based on clinical data from the Colibri-BPCO digital consultation that predicts excessive inactivity.

In this study, the GOLD standard EI was defined using clinical criteria summarized below. EI patients reported walking for an average of less than 10 minutes per day, and the pulmonologist judged on questioning that the DPA was indeed essentially "domestic." The objective of the MLA was to correctly classify EI subjects versus obviously active subjects hereafter referred to as Overtly Active (OA).

	Only Recreational	**Domestic**	**Fitness upkeep**
10 min.	EI*	Uncertain	Uncertain
10-30 min.	Uncertain	Uncertain	Uncertain
30-60 min.	Uncertain	OA*	OA
>60 min.	Uncertain	OA	OA

Classification of patients according to the physician – patient cross-judgement

**EI : Extremely inactive, OA : Overly active*

The MLA was validated on a test sample with an error rate of 13.7% (AUROC: 0.84, IC95% [0.75-0.92]). In the total population studied (n=1409), 34% of patients were finally classified as EIs, in line with the results of studies using actimetry as the GOLD standard.

Following the publication of this work[1] , we would like to verify the validity of the algorithm on a new population using the recognized GOLD standard: three-dimensional actimetry measurements.

ABSTRACT IN ENGLISH FOR CLINICALTRIALS.GOV

Title	Validation of a predictive algorithm for excessive inactivity (EI) in COPD patients by three-dimensional actimetry measurements
Collaborators (funding agency)	• Association pour la Complémentarité des Connaissances et des Pratiques de la Pneumologie (aCCPP) • Fondation Banque Populaire Auvergne Rhône-Alpes
Brief summary (10-12 lines)	Recently, we published an EI predictive Machine Learning algorithm based solely on clinical data, without any physical activity measures, collected from 1 409 patients. The GOLD standard of EI was defined on the basis of interrogation criteria. Patients considered as EI reported walking less than 10 minutes per day on average, and the pulmonologist judged that the patient had mainly "domestic activities". Despite the subjective nature of our GOLD standard, the algorithm validated on a test sample had an error rate of only 13.7% (AUROC: 0.84, CI95% [0.75-0.92]). In the total study population (n=1409), 34% of patients were ultimately classified as EIs by the algorithm, in agreement with the results of studies using actimetry as the GOLD standard. We now wish to verify and improve the validity of the MLA on a new smaller population of 104 patients, using a physiological GOLD standard such as three-dimensional actimetry.
Observational Study Model	☐Cohort ☐ Case Control ☐ Case Only ☐ Case Crossover ☐ Ecologic or community ☐ Family Based ☒ Other
Time Perspective	☐ Retrospective ☒ Prospective ☐ Cross sectional ☐ Other

[1] B. Aguilaniu et al. A machine learning approach to predict extreme inactivity in COPD patients using non-activity-related clinical data, PlosOne 2021

Number of arm(s) (write "1" if a single arm)	1
Number of groups and interventions	1
Follow-Up duration	1 year
Primary outcome measure	A contingency table recording the algorithm's performance metrics will be constructed in parallel with the actimetry data. The AUC-ROC will be used as the primary outcome to assess the performance of the algorithm.
Time point(s) at which primary outcome measure is assessed	September 2023
Secondary outcome measures*	n/a
Time point(s) at which Secondary outcome measure is assessed*	n/a
Inclusion criteria*	All patients with a diagnosis of COPD, all GOLD stages combined, who receive a properly informed Colibri-BPCO digital consultation.
Exclusion criteria*	• Patients receiving treatment for another unstable pathology, • Unstable patients: o Patients who had an exacerbation in the previous 2 months, o Patients who have had surgery, an infarction, a fall, or an accident limiting usual movements in the previous 3 months. o Protected patients within the meaning of the French Public Health Code (Code de la Santé Publique (CSP))
Number of subjects (or in each group)	104
Date of start and end of inclusions	January 2023 to July 2023

** Record only the top 2-3 secondary endpoints and the top 5-10 inclusion/non-inclusion criteria*

PROJECT SYNOPSIS

A. Title

Validation by three-dimensional actimetry measurements of a predictive algorithm for excessive inactivity in COPD patients

B. Sponsor

The aCCPP, association pour la Complémentarité des Connaissances et des Pratiques de la Pneumologie, represented by its President (Pr Christophe Pison) and Vice-President (Dr Eric Kelkel)

C. Site(s)

Pulmonologists (University Hospitals, General Hospitals, Private Hospitals) in Auvergne Rhône-Alpes and Alpes Maritimes, France

D. Objective

To validate a predictive algorithm for excessive inactivity in COPD patients using three-dimensional actimetry measurements.

E. Methodology

Recording of daily physical activities by three-dimensional actimetry for 7 consecutive days (WE included) in all COPD patients whose clinical data are collected on the digital consultation Colibri-COPD.

F. Number of subjects

104

G. Inclusion criteria

Any patient with a diagnosis of COPD, all GOLD stages combined, who receives a properly informed Colibri-BPCO digital consultation.

H. Exclusion Criteria

- Patients with other unstable conditions with treatment,
- Unstable patients:
  - who had an exacerbation in the previous 2 months,
  - Patients who have had surgery, a heart attack, a fall, or an accident limiting usual movements in the previous 3 months.
- Protected patients within the meaning of the French Public Health Code

I. Evaluation criteria & statistics

A contingency table recording the algorithm's performance metrics will be constructed in parallel from the actimetry data. The AUC-ROC will be used as the primary endpoint to judge the performance of the algorithm.

The statistical analyses performed will focus on measuring the performance of the prediction algorithm. The metrics used will be the following: Overall error, Accuracy, Positive Predictive Value, Negative

Predictive Value, Sensitivity, Specificity, AUPRC (Area Under the Precision and Recall Curve) AUROC (Area Under the Receiving Operating characteristic Curve). Precision and AUROC values will be presented with their 95% confidence intervals.

Clinical and functional characteristics of patients will be analyzed and compared by Kruskal–Wallis test and ANOVA for factors with ordered levels (ordAOV).

J. Information for the Scientific Council

- Study under the jurisdiction of the French Huriet law: NO
- Research not involving the human person (RIPH) (1, 2 or 3): 3

STUDY OR RESEARCH PROJECT BUDGET

A. Expenses

		Estimated budget
ACCPP: Project Sponsor		
1. Project structuring	Project coordination, budget management	*4.000,00 €*
	Drafting and submission of the protocol, information note, informed consent, drafting and submission of the annual report and the end of the study report	*4.000,00 €*
	Regulatory submission	*1.000,00 €*
	Production and archiving of the study's documents	*1.200,00 €*
	IT development	*3.600,00 €*
	Writing and publishing the article	*2.500,00 €*
2. Implementation, monitoring and closure	Recruitment and follow-up of investigators	*2.000,00 €*
	Monitoring of Colibri data	*3.000,00 €*
	Opening and closing of the centers	*3.800,00 €*
4. Data Management and Statistical Analysis	Analysis of the actimetry data and the algorithm	*5.500,00 €*
TOTAL ACCPP		**30.600,00 €**
ICADOM: ACCPP's subcontractor for the Pre-Inactiv project		
3. Performing actimetry	Flat rate of 195 Euros per patient, realized over 7 days	*19.500,00 €*
TOTAL ICADOM		**19.500,00 €**
TOTAL BUDGET		**50.100,00 €**

A. Funding

FUNDING €HT	
Category	**Amount**
CAPITAL RESOURCES	**20.100 €**
PATRONAGE	**30.000 €**
Fondation BP AURA	10.000 €
Other patron(s)	20.000 €
TOTAL FINANCING excluding valorizations	**50.100 €**

LIST OF RESEARCHERS PARTICIPATING IN THE RESEARCH

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20	Fedi	Arnaud	GHM of Grenoble	8 rue Docteur Calmette 38 000 Grenoble – France	+33476707272

PUBLICATIONS OF THE TEAM IN THE RELATED FIELD

1. Aguilaniu B, Gonzalez-Bermejo J, Regnault A, Barbosa CD, Arnould B, Mueser M. Disability related to COPD tool (DIRECT): towards an assessment of COPD-related disability in routine practice. Int J COPD. :12.
2. Aguilaniu B, Roche N. Erratum: The difficulties of measuring and improving physical activity in COPD. Npj Prim Care Respir Med [Internet]. 2014 Nov [cited 2018 Dec 22];24(1).
3. COLIBRI COPD Research Group, Roche N, Antoniadis A, Hess D, Li PZ, Kelkel E, et al. Are there specific clinical characteristics associated with physician's treatment choices in COPD? Respir Res [Internet]. 2019 Dec [cited 2019 Aug 28];20(1).
4. Guzun R, Aguilaniu B, Wuyam B, Mezin P, Koechlin-Ramonatxo C, Auffray C, et al. Effects of training at mild exercise intensities on quadriceps muscle energy metabolism in patients with chronic obstructive pulmonary disease: Mild-intensity exercise on muscle bioenergetics in COPD. Acta Physiol. 2012 Jun;205(2):236-46.
5. Kelkel E, Herengt F, Ben Saidane H, Veale D, Jeanjean C, Pison C, et al. COLIBRI: optimizing clinical practice and generating relevant scientific data. Rev Mal Respir. 2016 Jan;33(1):5-16.
6. Aguilaniu B et al. Digital consultation, machine learning & medical decisions: example of Colibri-pneumo. Breathing Info (2019)
7. Roche N. et al. Are there specific clinical characteristics associated with respiratory consultant's treatment choices in COPD? Respiratory Research (2019)
8. Roche N. et al. Trends over time in COPD treatment choices by respiratory consultants: An analysis from the COLIBRI-COPD French cohort. Respiratory Medicine (2019)
9. Aguilaniu B et al. A machine learning approach to predict extreme inactivity in COPD patients using non-activity-related clinical data, PlosOne 2021

PRESENTATION OF THE RESEARCH

A. Title

Validation by three-dimensional actimetry measurements of a predictive algorithm for excessive inactivity in COPD patients.

B. Objectives of the study or research

Main objective: To validate the Machine Learning algorithm predictive of EI in COPD patients using three-dimensional actimetry as the GOLD standard.

The main hypothesis:

is that the Machine Learning Algorithm developed from Colibri-Pneumo's real-life data is effective in classifying individuals according to their level of physical activity and in particular in detecting extremely inactive behavior.

Secondary objectives:

- To validate the GOLD standard "cross-judgment"
- To assess the influence of sedentary versus inactive time defined by three-dimensional actimetry on the prediction of EI behavior.

The second hypothesis:

is that the "standard GOLD" of Excessive Inactivity (EI) used to develop the predictive MLA does indeed correspond to an EI behavior, i.e., combining a high sedentary time and a very low level of daily physical activity.

C. Current status of the issue

It has been shown that COPD patients have a significantly decreased daily physical activity (DPA) compared to matched subjects. Moreover, the severity of inactivity is correlated with several prognostic indices such as the frequency of exacerbations, quality of life and mortality. These findings lead to the recommendation, with a level of evidence A, of DPA in the context of medically supervised respiratory rehabilitation programs and/or by encouraging patients to participate in programs promoting physical activity.

However, despite the established benefits, it is estimated that this rehabilitative care actually only involves 10% of the patients who should benefit from it. Among the various causes of this situation, the underestimation of excessive inactivity (EI) by pulmonologists is one of the causes of this care deficit.

Currently, only actimetry can accurately assess the patient's level of physical activity.

To alert pulmonologists to this excessive situation justifying priority care, without resorting to actimetry, we developed an AR predictive Machine Learning Algorithm based on clinical data from the Colibri-BPCO digital consultation.

In this study, the GOLD standard EI was defined using clinical criteria summarized below. EI patients reported walking for an average of less than 10 minutes per day, and the pulmonologist judged on questioning that the DPA was indeed essentially "domestic." The objective of the MLA was to correctly classify EI subjects versus obviously active subjects hereafter referred to as Overtly Active (OA).

	Only Recreational	Domestic	Fitness upkeep
10 min.	EI*	Uncertain	Uncertain
10-30 min.	Uncertain	Uncertain	Uncertain
30-60 min.	Uncertain	OA*	OA
>60 min.	Uncertain	OA	OA

Classification of patients according to the physician – patient cross-judgement

**EI : Extremely inactive, OA : Overly active*

The ML algorithm was validated on a test sample with an error rate of 13.7% (AUROC: 0.84, CI95% [0.75- 0.92]). In the total population studied (n=1409), 34% of patients were finally classified as EIs, in line with the results of studies using actimetry as the GOLD standard.

Following the publication of this work[2] , we would like to verify the validity of the algorithm on a new population using the recognized GOLD standard: three-dimensional actimetry measurements.

D. Short bibliography on the theme

1. Watz H, Pitta F, Rochester CL, Garcia-Aymerich J, ZuWallack R, Troosters T, et al. An official European Respiratory Society statement on physical activity in COPD. Eur Respir J. 2014; 44(6):1521-1537.
2. Furlanetto KC, Donária L, Schneider LP, Lopes JR, Ribeiro M, Fernandes KB, et al. Sedentary Behavior Is an Independent Predictor of Mortality in Subjects With COPD. Respir Care. 2017;62(5):579-587.
3. Rabinovich RA, Louvaris Z, Raste Y, Langer D, Van Remoortel H, Giavedoni S, et al. Validity of physical activity monitors during daily life in patients with COPD. Eur Respir J. 2013;42(5):1205-1215.
4. Schneider LP, Furlanetto KC, Rodrigues A, Lopes JR, Hernandes NA, Pitta F. Sedentary Behaviour and Physical Inactivity in Patients with Chronic Obstructive Pulmonary Disease: Two Sides of the Same Coin? COPD J Chronic Obstr Pulm Dis. 2018;15(5):432-438.
5. Van Gestel AJR, Clarenbach CF, Stöwhas AC, Rossi VA, Sievi NA, Camen G, et al. Predicting Daily Physical Activity in Patients with Chronic Obstructive Pulmonary Disease. Morty RE, editor. PLoS ONE. 2012;7(11):e48081.
6. Weng SF, Reps J, Kai J, Garibaldi JM, Qureshi N. Can machine-learning improve cardiovascular risk prediction using routine clinical data? Liu B, editor. PLOS ONE. 2017 4;12(4)e0174944

[2] B. Aguilaniu et al. A machine learning approach to predict extreme inactivity in COPD patients using non-activity-related clinical data, PlosOne 2021

E. Application perspective

- If the validation of the algorithm is obtained by the actimetry measurements:
  - We will submit a second article;
  - We will test on a new cohort whether the addition of additional easily accessible variables (*simple podometry*; *3-MINUTE CRT Assesment of work functioning*) improves the predictive power and especially the sensitivity of the MLA.
  - We will integrate this validated algorithm into the Colibri-BPCO consultation in order to alert the pulmonologist to the risk of extreme inactivity. It will allow COPD patients, whose quality of life is degraded due to this undetected extreme inactivity, to be directed towards an adapted care.
- In the event that the algorithm is not validated, we plan to mine the data to reconstruct a new algorithm. A new validation study will then be necessary.

PROTOCOL DESCRIPTION

A. Type of cohort

This is a prospective, diagnostic cohort study for COPD patients (all GOLD severity stages) with the aim of promoting the care management of excessive inactivity, which is a common goal in most chronic respiratory diseases.

B. Materials and Populations

Equipment: actimetry sensors

The study requires the use of accelerometers, and of a software to analyze the accelerometers' data. They are the property of Icadom, the aCCPP's subcontractor for the realization of the actimetry.

Accelerometer data:

- Model Actigraph, wGT3x-BT
- CE marking
- Complies with the Council Directive 93/42/EEC concerning medical devices

Data for the data analysis software:

- Name : Actilife 6.
- The software collects and provides access to the following data:

Epoch; Weight; Age; Gender; Date; Hour; Day of week, Day of week num, kcals; METs ;Bouts ;Total time in Bouts; Avg time per bout; Total counts in bouts; bout start; bout end; time in bout; sedentary bouts; total time in sedentary bouts; avg time per sedentary bout; sedentary bout start; sedentary bout end; time in sedentary bout; time since last sedentary bout; Sedentary; light, moderate, vigorous, very vigorous; total MVPA; %MVPA; Average MVPA; In bed Date; In bed Time; Out bed Date; Out bed Time; Onset Date; Onset Time; Latency; Efficiency; Total Minutes in Bed; Total Sleep Time (TST); Wake After Sleep Onset (WASO); Number of Awakenings; Average of awakening length; Axis 1 counts, Axis 2 counts; Axis 3 counts; Axis 1 average counts; axis 2 average counts; axis 3 average counts; Axis 1 max counts; axis 2 max counts; Axis 3 max counts; Axis 1 CPM; Axis 2 CPM Axis 3 CPM; Vector Magnitude counts; Vector Magnitude Average Counts; Vector Magnitude Max Counts; Vector Magnitude CPM; Step Counts; Steps Average Counts; Steps Max Counts; Steps per minute; Lux average Counts; Lux Max counts; Number of Epochs; Time; Calendar Days; Wear Time Start; Wear Time End.

Data collected by the actimetry sensor and available on the analysis software are de-identified using a research-specific code number.

Only the Icadom project manager has access to the correlation table between the patient identity and the code. The patient's identifying data are stored on a health data host certified for the 6 HDS levels.

Hardware: e-CRF

The e-CRF used corresponds to the content of the Colibri-BPCO digital consultation (available on www.colibripneumo.fr for pulmonologists) slightly amended to meet the needs of the study:

- The data required for the study, to be entered in the fields of the digital consultation intended for this purpose, are the following:
    - Daily walking time (out-of-home, patient-rated): < 10 min. / 10-30 min. / 30-60 min. / > 1h
    - Activity classification (assessed by physician): Solely domestic / Recreational (significant activity out-of- home) / Fitness upkeep
    - Smoking yes/no
        - If yes: active / completely weaned
    - Number of pack-year
    - History / Comorbidities
    - Current medications
    - Exacerbations in the past year: number and severity (mild, moderate, severe, uncertain)
    - Clinical > Dyspnea (MRC SCALE)
    - Chronic cough: Never / Intermittent / Frequent / Permanent
    - Expectoration (frequency): Never / Intermittent / Frequent / Permanent
    - Weight
    - Size
    - RFE measurements: FEV1, FVC
    - Questionnaires > CAT, DIRECT, HADS

- After completing the digital consultation during the patient interview, investigators will have access to a study-specific modal window. It will allow them to collect the patient's contact information, present the non-inclusion criteria, print information notes and collect the patient's informed consent.

Only investigators have access to the patient's identifying data. Each patient has an identification number in Colibri, indicating the order of creation of the patients. It is this "ID" number that will appear during data exports and that will be used for research.

All data entered are stored on a secured server certified for the storage of health data. The database has been authorized by the French Commission on Information Technology and Liberties (CNIL, authorization number #2013-526) after a favorable opinion from the Advisory Committee on Information Processing in Health Research (CCTIRS).

Population

Any patient with a diagnosis of COPD, all GOLD stages combined, who receives a properly informed Colibri-BPCO digital consultation.

Main criteria for non-inclusion:

- Patients with other unstable conditions with treatment,
- Unstable patients: with an exacerbation in the previous 2 months,
- Patients who have had surgery, a heart attack, a fall, or an accident limiting usual movements in the previous 3 months,

- Protected patients within the meaning of the French Public Health Code.

C. Methodological approaches and patient number calculation

Definition of Prevalence in the study sub-population

The sample size and the prevalence of EI behavior influence the sensitivity and specificity of the algorithm. The prevalence of EI behavior in COPD patients, studied by actimetry sensors, is estimated to be around 30%. The published ML predictive algorithm suggests an EI prevalence of 34%.

Sensitivity

The selected sensitivity is 79.4%, which corresponds to the sensitivity of the current algorithm.

Target width

The target width chosen for the CI95% is +/-15

Calculation of the number of patients to be recruited

With these parameters, the required sample size is 94 patients. Assuming a dropout rate of 10%, we obtain a sample size of 104 patients.

D. Evaluation criteria

Reminder of the main objective: To validate the Machine Learning Algorithm predictive of EI in COPD patients using three-dimensional actimetry as the GOLD standard.

Primary endpoint (related to the primary objective)

A contingency table recording the algorithm's performance metrics will be constructed from the GOLD Standard actimetry. The AUC-ROC will be used as the primary endpoint to judge the performance of the algorithm. The algorithm will be validated if the AUC-ROC is greater than or equal to 0.80, CI95% [0.65- 0.95].

Reminder of secondary objectives:

- To validate the GOLD standard "cross-judgment”
- To assess the influence of sedentary versus inactive time defined by three-dimensional actimetry on the prediction of EI behavior.

Evaluation criteria for secondary objectives

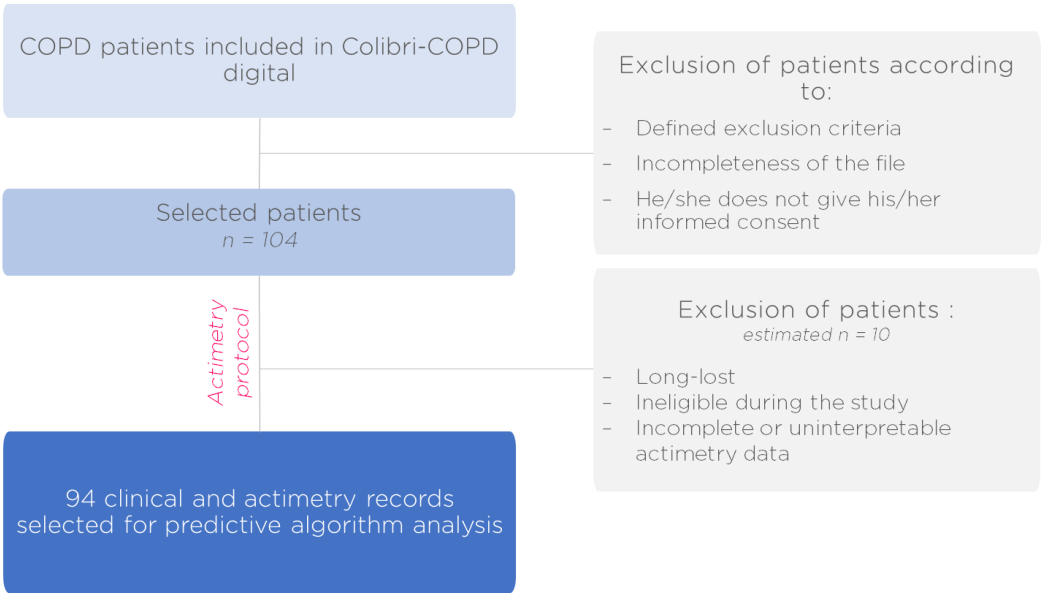
- A contingency table recording the metrics of GOLD Standard performance "cross-judgment" will be constructed from the GOLD Standard actimetry. The AUC-ROC will be used as the primary endpoint to judge the performance of the GOLD standard. The GOLD standard will be validated if the AUC-ROC is greater than or equal to 0.80, CI95% [0.65- 0.95].
- Discriminant analysis of explanatory variables in the predictive MLA.

E. Primary and associated factors whose influence is assessed

The study will evaluate as secondary objectives the influence of sedentary time and inactive time, as defined by three-dimensional actimetry on the prediction of EI behavior.

F. Main experimental steps

Study Flowchart:



Steps:

Only one consultation is necessary to collect all the patient's data. Three-dimensional actimetry measurements are taken over 7 consecutive days, including weekends.

Step 1: the investigator completes a Colibri consultation, informs the patient and collects his or her informed consent. A minimum delay of one hour must be respected between the time of the information and the informed consent. However, it is possible that the patient does not stay one hour at the pulmonologist's office. To guarantee this right, the Icadom operational team ensures that the patient gives his or her informed consent at the time of the call.

The name of the investigating physician, the date and time of the collection of the informed consent to participate in the study and to the processing of personal health data for research purposes are saved in the patient's digital medical record. The date of the call from Icadom and the confirmation of the informed consent will also be saved

Step 2: The informed coordinator checks the completeness of the digital consultation.

Step 3: The patient completes the HADS, MRC SCALE, DIRECT, CAT questionnaires.

Step 4: The Icadom team contacts the patient to set up the actimetry sensor. The team answers the patient's questions and makes sure that he gives his informed consent.

Step 5: Sending of the actimetry sensor. Wearing by the patient, return on D+7.

Step 6: Entry of the actimetry results on a dedicated application

Step 7: Data Analysis

Total duration of the study: 1 year

The various stakeholders of the project have developed complementary expertise, ensuring the smooth running of the project:

- Project coordination: A. Rigal and D. Hess from the aCCPP
- Realization of the actimetry : J.C. Borel's team, from Icadom
- Machine Learning and predictive statistics expertise: Pr. Anestis Antoniadis, Sophie Lambert-Lacroix
- Exercise and COPD expertise: Pr. B. Aguilaniu for the aCCPP

G. Risks, constraints and expected benefits

The actimetry sensor has the appearance of a watch (weight: 19 grams). It is worn without connection to the skin, on the belt, continuously during the day. The device is designed to be disturbance-free and does not present any risk.

The only constraint is that it must be worn during the day for 7 consecutive days.

The expected benefits are multiple:

- It allows the physician to obtain objective data on the level of physical activity of his patient, allowing him to direct inactive patients to an adapted care. The quality of life of the patient is thus improved.
- More broadly, this study aims to validate an algorithm for predicting extreme inactivity. Used in consultation, this simple and reliable measure could eventually replace actimetry without requiring the involvement of the patient.

H. Follow-up of the French HURIET law guidelines

N/A

I. Key words

COPD, Physical inactivity, Medical decision, Machine Learning

J. Suggested experts

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GLOSSARY

aCCPP: Association pour la Complémentarité des Connaissances et des Pratiques de la Pneumologie

AUPRC: Area Under the Precision-Recall Curve

AUC ROC or AUROC: Area Under the Curve" of the "Receiver Operating Characteristic" curve

COPD: Chronic Obstructive Pulmonary Disease

CAT: COPD Assessment Test

COPD: Chronic Obstructive Pulmonary Disease

DIRECT: DIsability RElated to COPD Tool

DPO: Data Protection Officer

EI: Extremely Inactive

GOLD : Global initiative for chronic Obstructive Lung Disease

HADS: Hospital Anxiety and Depression Scale

MRC Scale: Medical Research Council Scale

OA: Overtly Active

3-minute CRT: 3-minute chair rise test