Title :

Point-of-Care Ultrasound use by general practitioners in France.

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Introduction

I. Background

In the last decade, the concept of point-of-care ultrasound (POCUS) has emerged, as un ultrasound performed and interpreted directly by the clinician in the office or at the bedside depending on the specialty. The development of portable, affordable and battery-powered devices has made them easily accessible to clinicians. In our study, POCUS is defined as the ultrasound exam performed in the office by the clinician during physical examination.(1–5)

II. Evolution of the use of POCUS

POCUS is an extension of the physical examination. It completes it, yet it does not replace it. It answers a specific question promptly and offers a better understanding of the pathophysiological context (6).It was first used in the intensive care and emergency departments, then in internal medicine, where integrated to clinical reasoning, it helps the diagnostic process by reducing the tentative diagnoses, optimizes the care pathway, increases the care safety and improves cost-effectiveness (7–9). Even in inexperienced hands, clinical examination integrating POCUS is more sensitive and specific than clinical examination alone for many clinical findings such as hepatosplenomegaly, intrauterine pregnancy, abdominal effusion, pleural effusion, or lung damage in the context of COVID-19. The use of POCUS is considered as the 5th pillar of the physical examination: inspection, auscultation, palpation, percussion and insonation (9–13).

A systematic review of the literature in 2019 highlighted the increased interest of general practitioners in the use of POCUS as well as in medical training. A consensus with thirty indications specific to primary care was obtained among Danish, Norwegian, Swedish and Finnish general practitioners, including precisely 8 musculoskeletal, 5 abdominal, 3 soft tissue, 5 obstetrical and gynecological. In Norway, POCUS is reimbursed for general practitioners for 7 indications since 2009 (14–19).

III. POCUS in General Practice

At the moment, there are few studies describing the use of POCUS in general medicine. Most of them are descriptive studies made more than ten years ago while recent technological development has resulted in better quality images. There is no study with high level of evidence, and the majority of the literature is made of descriptive reports based on the activity of a small number of physicians (20–23).

Unlike other countries, France has currently no recommendations on the modalities of use for POCUS. There are no guidelines on the GP curriculum nor on the appropriate equipment for general practitioners, nor on the certification process.

In the current state of knowledge, it seems relevant to establish an overview of the practice of POCUS in general medicine in France. This work is part of an international European reflection on the use of POCUS in general practice and its role in the diagnostic process, therapeutic process and the patients' care pathway in Denmark, in Norway and in France. Comparison of the use of POCUS by the GP is possible between these countries with similar medical practices, but each country will have its own specificities due to the differences between their healthcare systems (19).

The current protocol was written in collaboration with the GP Research Unit of Aalborg. The first part of the protocol was completed between January 2018 and July 2019 in Denmark, registered at clinicaltrials.gov NCT03375333. This part of the protocol constitutes the French study.

Aim of the study

The aim of this study is to describe the use of POCUS and its role in the diagnostic and therapeutic process in general medicine.

● Description of the use of POCUS through indication, organs scanned, findings, frequency, time consumption.

● Analysis of the role of POCUS in the diagnostic process: change of diagnostic hypotheses and change of certainty in the main diagnostic hypothesis.

● Analysis of the role of POCUS in the therapeutic process: change in the care pathway and the therapeutic initial plan.

Trial design

A prospective observational cohort study.

I. Study setting

The study will take place in France among GPs that use POCUS during consults in their office or during home visits.

II. Investigators recruitment

a. Eligibility criteria

GPs practicing POCUS in rural or urban areas, alone or in groups with fixed or portable devices will be eligible.

b. Recruitment

A list of 150 eligible general practitioners currently practicing POCUS has been pre-established, most of whom have previously participated in general practice research.

Another recruitment channel will be the "POCUS in General Practice" working group of the French College of General Practice, which includes representatives from all affiliated organizations offering ultrasound training to their members. Members of these organizations will be invited to participate via email.

Physicians not listed initially may also be recruited during general congresses. A questionnaire will be sent to these physicians to verify inclusion criteria.

General practitioners will be selected by random draw from among eligible respondents.

From the responding physicians, we will recruit 60% who practice in the Île-de-France region. If the number of interested physicians in Île-de-France proves insufficient, recruitment may be expanded to other regions of France, giving priority to geographic diversity.

Similarly, if initially recruited physicians fail to participate, recruitment may be extended to eligible physicians from other regions of France to ensure an adequate number of patient inclusions for the study.

c. Sample size

According to the data from a pilot study, POCUS is used for 5 to 7% of GP consultations, which corresponds to 1 or 2 POCUS for 25 consultations(14). During the 22-day inclusion period, we expect that every GP performs between 22 and 44 POCUS exams, which makes an expected total of 660 to 1,320 POCUS. We estimate that 70% of the POCUS performed can be included. The number of investigators planned is comparable to the Danish study in which 20 GPs participated and approximately 600 POCUS exams (30 ultrasounds / doctor) were completed during the inclusion period which lasted 1 month. The total number of POCUS expected is sufficient for a valid statistical description.

d. Inclusion criteria

The GPs must fulfil the following criteria:

- minimum use of POCUS on two anatomical areas
- GP activity for minimum two days / week
- A minimum of two scanning probes
- Previous participation in formal education in the use of POC-US
- Minimum six-month experience with POCUS in general practice.
- Estimated use of POCUS on a daily basis (average)

e. Exclusion criteria

GPs will be excluded from the study in the following situations :

- Conflict of interest involving the participating physician
- Participation in the research group or scientific advisory board
- Direct financial interest in the sale or promotion of ultrasound devices
- Inclusion of fewer than 5 patients, assessed at the end of data collection
- Exclusive practice of scheduled ultrasounds only (i.e., ultrasounds performed during dedicated, pre-planned consultations specifically arranged for that purpose, whether or not requested by another practitioner)
- Change in professional activity between recruitment and the start of patient inclusion (e.g., stopping the practice of general practice or discontinuing the use of POCUS)

f. Ultrasound Training of Investigator Physicians

Each physician will be asked to provide a detailed description of their ultrasound training, including:

- The name of the diploma or certification
- The modules completed
- The year of completion

● The number of hours of theoretical and practical training

● An estimate of the number of supervised examinations (if applicable)

III. Patient inclusion

Any patient having a POCUS examination during a general practice consultation by one of the GPs may be included in the study. Patients must provide written informed consent before being included. They will be informed about the study terms by the investigator physician and through a notice displayed in the waiting room.

Patients will be excluded if they refuse to participate in the study, are minors, are unable to provide informed consent, or if the ultrasound performed is a scheduled examination. Refusal to participate in the study will not affect the patient's medical care.

In the case of a patient exclusion, the investigator physician must record the patient's age, sex, and the reason for exclusion in a designated log.

If a second POCUS examination is performed at a later date for a patient already included, the data from that subsequent exam will not be collected. Only the data from the patient's first examination will be included. The additional ultrasound will be listed in the table of excluded ultrasounds.

IV. Participants withdrawal

Investigating GPs and patients can withdraw consent from the study at any time and for any reason. The investigator may also exclude participating GPs if they do not wish or cannot follow the study procedures.

V. Intervention

There will be no intervention in this study. The GPs included already use ultrasound during their physical examination. The data recorded for this study will reflect the daily practice of general practitioners using POCUS. There will be no additional exams or other ways to change the patient management. If a second POCUS is performed later for the same patient, this data will not be collected. Only data from the patient's first examination will be collected.

VI. Data collection

Each investigator will collect data about every POCUS examination performed during the inclusion period of 22 consecutives working days.

a. Registration tool development

a) Initial questionnaire design

The data collection tool is based on the questionnaire originally developed by the Center for General Practice at Aalborg University in Denmark from literature data, a dialogue with the "Ultrasound group of the Danish College of General Medicine" and an interview study. The registration tool was developed as a questionnaire to be used before and after the GP uses POCUS in the consultation. A time log is included to ensure that the questionnaire has been completed before and after the exam.

b) Translation and adaptation to general practice in France

For this study, the questionnaire will first be translated into French and then back-translated (reverse French-English translation) by two bilingual translators separately. The result of the back-translation will be analyzed and a second French version will be submitted to French

general practitioners practicing POCUS and members of the “Ultrasounds group of the College of General Medicine” in France. For each theme of the questionnaire, there will be a common part of questions, to ensure the comparability of the results between the different European countries. An additional set of questions relevant to general practice in France will be discussed and validated by the French College of General Medicine. The acceptability and validity of the questionnaire will be tested during focus groups (26).

c) Registration tool

The GPs will be asked to fill a questionnaire in the online database SurveyXact each time they use POCUS during their daily work. The data will be registered electronically in SurveyXact with a time log to ensure a before and after registration.

The GPs can access the questionnaire on their mobile phone, iPad or computer, using a unique link (respondent link) allocated to each participant. A key file, connecting each GP participant with the respondent link in SurveyXact (link), will be safely stored at Center for General Practice at Aalborg University, Denmark.

The GPs will give each patient a unique ID-number. A key file connecting this ID-number and the patient's identity will be safely stored at the GP’s clinic.

b. Time log

We will register date and time, when the GP starts filling the questionnaire and finishes the final question. Furthermore, we will create a variable with the exact time between “before” and “after” questions. If GPs use less than one minute on this page and the GP registers a duration of the POC-US > 1 minute, we will assume that there was no “before and after” registration, but only an “after” registration. In that case, we will exclude the “before” answers.

c. Participants retention

In order to calculate the participant retention rate, defined by the proportion of eligible patients included in the study, we will ask the GP to record age and gender for each patient eligible but not included in the study (time constraints, patient refusal or other reasons).

d. Data management

Data will be saved electronically on the SurveyXact server and on a server at Aalborg University and will only be accessed by the research group using personal passwords. The patient key file and consent forms will be safely stored at the GPs’ office and the research group will not have access to this information during the study.

Any paper editions of the registration tool or questionnaire (in case of server breakdown) will be safely stored at the GPs office until the end of the data collection. Afterwards, they will be safely stored at the General Practice Department of Sorbonne University, 27 rue de Chaligny, PARIS 75012, FRANCE. The data will be securely stored for two years following publication, after which they will be destroyed. The database itself will be archived for 15 years before being destroyed.

e. Data monitoring

During the study, the research team will monitor the enrollment of patients for each GP. Each practitioner will receive support throughout the study implementation, with at least five follow-up appointments :

- Initial meeting : Conducted either individually via Zoom, during which the study will be presented using an informational document.

- Pre-inclusion appointment (Day -1 before enrollment begins) : This session will test the online questionnaire, address practitioners' questions, and clarify details regarding the required documents.

- Day 7 appointment (post-study start) : To ensure that practitioners are not experiencing difficulties, fully understand the recruitment procedures, verify initial enrollment data, and identify potential errors, duplicates, or challenges encountered.

- Day 14 appointment : To review progress, confirm that recruitment is proceeding smoothly, and verify initial data collection, as well as detect any errors, duplicates, or issues.

- End-of-inclusion appointment : To review any difficulties faced, discuss the number of patients enrolled and excluded, and provide information regarding the documents to be sent back, those to be retained, and their retention duration.

f. Data coding

The physicians' diagnostic hypotheses will be entered as free-text responses in the questionnaire.

To facilitate epidemiological analysis and standardize the data, these diagnoses will be translated into coded data using the International Classification of Primary Care, 2nd edition (ICPC-2). This is the French version of the classification system developed by the World Organization of Family Doctors (WONCA).

g. Statistical analysis

● Descriptive analyses

Descriptive analyses will be performed using RStudio software. For quantitative data, most will be summarized using means and standard deviations if they follow a normal distribution, and medians and interquartile ranges if they do not. Qualitative data will be expressed as percentages. Bar charts will be created to represent the various organs examined by the physicians.

● Comparative analyses

Statistical comparative analysis will be conducted using RStudio software.

For these analyses, we will exclude patients for whom the POCUS time recorded on SurveyXact is less than 60 seconds between completing the first questionnaire and the second. We will consider that there was no response before and after, only an "after ultrasound" response.

Data collection will primarily rely on nominal variables. Categorical variables will be described using contingency tables.

To assess the relationship between paired variables, we will use the Mac Nemar test. To compare the characteristics of included and excluded patients, we will use a Chi-2 test. Results will be considered statistically significant if the p-value is less than 0.05. For highly significant results with p-values much lower than 0.05, we will simply report $p < 0.01$.

h. Ethics

This study falls under the Jardé law and qualifies as a Category 3 study. This is an observational, non-interventional study, and the procedure under investigation (POCUS) is used in the "usual practice", without altering the management of study participants. In accordance with the General Data Protection Regulation (GDPR), a MR004 compliance

declaration was submitted to the Data Protection Officer (DPO) of Sorbonne University. The protocol received approval from the Sorbonne University Research Ethics Committee, and a declaration was filed with the CNIL in May 2022.

i. Good clinical practice

GPs will be asked to present a “Good clinical practice” certificate in order to complete their investigator file.

j. Confidentiality

All GPs will be subject to a confidentiality agreement.

k. Declaration of interest

All GPs and investigators will sign a conflict of interest declaration.

Results

I. Characteristics of the participating GPs

Each investigator physician will complete a questionnaire hosted on LimeSurvey, which will collect the following information:

● Their contact details

● Their practice address

● Their typical weekly schedule (number of half-days worked)

● Their type of practice (e.g., participation in SOS Médecins, office-based or home visits)

● Their experience and detailed ultrasound training (name of the diploma or certification, modules completed, year of completion, number of hours of theoretical and practical training)

● Their ultrasound equipment (type of machine and type of probe)

● The anatomical regions they routinely assess using POCUS

● Whether they serve as ultrasound trainers

● Whether they supervise medical students (level 1 or 2 residents, or medical externs)

● Their involvement in the university department of general practice

The purpose of this questionnaire will be, first, to verify the physicians' eligibility criteria, and second, to describe the profile of general practitioners currently using clinical POCUS.

II. The use of POCUS in General Practice

We will describe the ultrasound indications, organs explored, findings, frequency of use and duration of the examination.

a. Indications

The indications of POCUS will be described through the GP's intention regarding ultrasound:

● to answer a specific clinical question (yes / no / maybe) and document the answer in the medical file

● to conduct therapeutic education

● to monitor or control an ultrasound finding

● to screen an asymptomatic patient

● to scan to improve technical ultrasound skills without any clinical profit

● to perform a diagnostic scan with a detailed description of anatomical regions and provide a complete diagnostic report

b. Documented organs

The frequency of the different POCUS examinations will be summarized in relation to the organs scanned. The performed POCUS examinations are defined as organs scanned and not as standardized procedures such as FAST, FATE or LUS since there might be differences in the definition and interpretation of these examinations. The organs scanned are registered on a list of organs in the questionnaire. The possibilities in this list originate from interviews with GPs using POCUS and from Danish pilot testing. This list will be discussed during a focus group of French GPs using POCUS. The GPs will be allowed to write in free text if organs are missing from the list.

c. Ultrasound findings

POCUS findings will be measured through the following categorical variables:

● certain positive findings

● uncertain positive findings

● certain negative findings

● uncertain negative findings

● incidental findings

d. Frequency

The frequency of POCUS use will be described as the number of GP consultations where POCUS is used over the total number of GP consultations per day during a 22 consecutive days.

Each participant will provide information on the total number of face-to-face consultations she or he has had during the study period. If the GP uses a portable or ultraportable ultrasound device during home visits, they will be included in the total number of consultations.

e. Time consumption

The GPs will measure the time used for the POCUS examination. The time registration starts when the scanning begins and ends when the scanning has been finished. Hence, it will only include the duration of the POC-US examination, not information about the scanning or other elements of the consultation. This time registration will be described in minutes for each type of POC-US examination.

III. Role of POCUS in the diagnostic process

We will describe the main diagnostic hypothesis recorded before and after POCUS, the total number of diagnostic hypotheses recorded before and after POCUS, the change in the total number of diagnoses hypotheses, the change in the GP's confidence in the diagnostic hypotheses (5-point Likert scale).

a. Change in diagnose

The GPs are asked to declare before the use of POCUS:

- one main diagnostic hypothesis
- other diagnostic hypotheses

After the use of POCUS, the GPs will be shown their “Before-POCUS” diagnostic hypothesis and asked if these diagnoses have changed. If the diagnoses have changed, they will be asked to specify them.

The diagnostic hypotheses are registered as detailed free text in the questionnaire. The corresponding ICPC-2 (International Classification of Primary Care-2) codes will be coded from the free text by the research team.

The observed change in the diagnostic hypotheses will be described by the frequency of declared diagnostic hypotheses changes and the overall registered change in the ICPC-2 codes. Overall registered change in the ICPC-2 codes are defined as:

- Change in the ICPC-2 code of the main diagnostic hypothesis after US
- Change in all possible ICPC-2 diagnostic hypotheses after the use of POC-US
- Change in the total number of diagnostic hypotheses
- Change from symptom diagnosis to disease diagnosis after POC-US

b. Change in confidence

The GPs are asked to register any change in their confidence in the diagnostic hypothesis after the use of POCUS by choosing one of the following variables on an ordinal scale:

- increased confidence
- more confident
- unchanged confidence
- less confident
- reduced confidence

IV. Role of POCUS in the therapeutic process

We will describe the patient’s plan before and after POCUS and the planned treatment before and after POCUS. We will describe the relationship between the ultrasound findings and the change in the patient management (diagnostic process, treatment, care pathway). The diagnostic and therapeutic modifications will be described by the frequency of responses or by the change in the total number of responses.

The statistical analysis will be descriptive. Data collection will mainly be done using nominal variables. However, the variable "GP’s confidence in the diagnostic hypotheses" will be

measured by an ordinal variable, “the duration of the examination" and "the patient's age" by a continuous variable.

The categorical variables will be described using contingency tables and Chi-2 test and Fisher's exact test will be used to test the relationship between the variables. If the continuous variables follow the normal distribution, they will be described with means and either a standard deviation or a 95% confidence interval of the mean. If they are not normally distributed, they will be described with a median and interquartile range.

a. Change in the therapeutic plan for the patient

The GPs will register their plan for the patient by choosing one or more of the following categorical variables before using POC-US:

- acute admission to hospital
- subacute referral to hospital
- normal referral to hospital
- subacute referral to specialist
- normal referral to specialist
- referral for radiology
- other referral (e.g. to physiotherapist, etc)
- follow-up in the clinic
- no plan for follow-up
- other

After using POC-US the GP is shown the “before POC-US plan for the patient” and asked if this plan has changed. If the plan has changed, the GP is asked to specify.

Change in the plan for the patient is defined as the frequency of declared change after registration from one possible answer to another or change in the total number of possible answers.

b. Change in the planned treatment

The GPs register their planned treatment before POCUS by choosing one or more of the following categorical variables:

- medical treatment
- non-medical treatment
- no treatment
- other

After using POCUS, the GP is shown the “before POC-US planned treatment for the patient” and asked if this planned treatment has changed. If the planned treatment has changed, the GP is asked to specify.

Change in the planned treatment of patients is defined as the frequency of declared change described before and after registration from one possible answer to another, or in the total number of possible answers.

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