How Point-of-Care Ultrasounds Affects the Diagnostic Process in General Practice. A prospective follow-up study.

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Registration:

The study will be registered at clinicaltrials.org.

Funding:

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Research question: What is Point of Care Ultrasound (POC-US) used for in general practice in Denmark and how does it affect the diagnostic process and treatment of patients?

Population: Patients listed with a general practice in Denmark, in whom the general practitioner (GP) uses POC-US.

Intervention: None, this is an observational study.

Comparison: None.

Outcome: Indications and frequencies of the performed POC-US examinations, change in tentative diagnosis, plan, and treatment before and after the use of POC-US in relation to GP characteristics, confidence in the tentative diagnosis, findings and quality of the POC-US examination.

Time: Each GP collects data for one month and there is a follow-up after six months

Introduction:

Background and rationale

Traditionally ultrasound (US) examinations required large expensive devices and were performed by highly trained specialists to provide a full anatomical description of an organ or pathological findings. This is known as "Diagnostic US". As the US devices became smaller, cheaper, and better, the use of US disseminated and became integrated in most medical areas as point of care ultrasound (POC-US) [1]. POC-US is a focused US scan for a predefined condition and it is performed by healthcare professionals trained to use POC-US to answer simple clinical question, typically with yes-no answers e.g., "is there a gallstone?" Thus POC-US is an extension of the physical examination of the patient, where positive and negative findings are evaluated in context with the patient's signs and symptoms and the result is noted in the patient's medical record similar to how auscultation findings are recorded when using the stethoscope.[2]

Potentially there are great advantages of using POC-US: It may improve success in US guided procedures e.g. vascular access[3], it may lead to more correct diagnoses [4], and supplement or replace more advanced imaging[5]. It may also facilitate screening, e.g. of abdominal aorta aneurism [6] in high risk patients. However, an increased use of US imaging may lead to overdiagnosis [7], spurious findings, incidental findings or diagnosing of clinically unimportant conditions. US is a user-dependent technology that requires appropriate training and quality assurance. Misinterpretations may lead to flawed diagnoses that could raise an unnecessary concern in patients; and even worse, it could delay proper treatment if a serious condition is overlooked and the scanning health care professional and patient feel confident that everything is fine. It may also lead to false positives including potential harmful downstream procedures.

From the *Danish College of General Practitioners (DSAM) interest group in POC-US* we know that only few Danish GPs use POC-US and among those there is a great variation in the education, experience, and application of the method [8]. The DSAM POC-US group has suggested a curriculum for POC-US [appendix 1], and Bitsch et al [9] have proposed a guideline for the use of POC-US, but it is not known to what extent these recommendations have been adapted.

There are only few articles describing the use of POC-US in general practice [5,6, 10-59]. Most of the studies are more than 10 years old [23-59] and the development in technology may have improved the images that can be obtained by present-day equipment. No randomized trials have been carried out. Most of the studies are descriptive reports with only a few enthusiastic GPs, who might not be representatives for GPs in general.

The use of POC-US:

The literature describes that POC-US is used on very different indications, on different organs and with a great difference in the level of details obtained through POC-US examinations. Most commonly reported are obstetric, gynecological, and abdominal scans. In addition, POC-US was used to estimate the ejection fraction of the heart. Table 1 summarizes the application in the studies:

Table 1

Application	Number of studies	Reference
Abdomen	14	[5,6,18,23,30,32,34,35,36,43,44,46,58,59]
Heart	7	[5,17,26,31,34,37,56]
Lung	3	[55,11,46]
Gynaecology	7	[18,30,34,35,36,44,58]
Obstetric	17	[18,21,22,29,30,33,35,36,39,40,43,47,48,49,50,51,57]
Sinusitis	3	[28,41,54]
Musculoskeletal	3	[8,35,53]
Carotid arteries	1	[34]
Thyroid	2	[34,35]
Neck	1	[35]
Mamma	1	[35]
Male pelvis	3	[18,23,35]

In different studies the POC-US examinations were used differently and described with varying levels of details. A recent study described POC-US as being used to confirm or dismiss a clinical hypothesis [5], whereas other studies describe a full anatomical assessment of several organs [35,36,45] . We do not know how Danish GPs scan, which organs or positions they select or if the Danish GPs restrict themselves to scan within the curriculum suggested by the DSAM group.

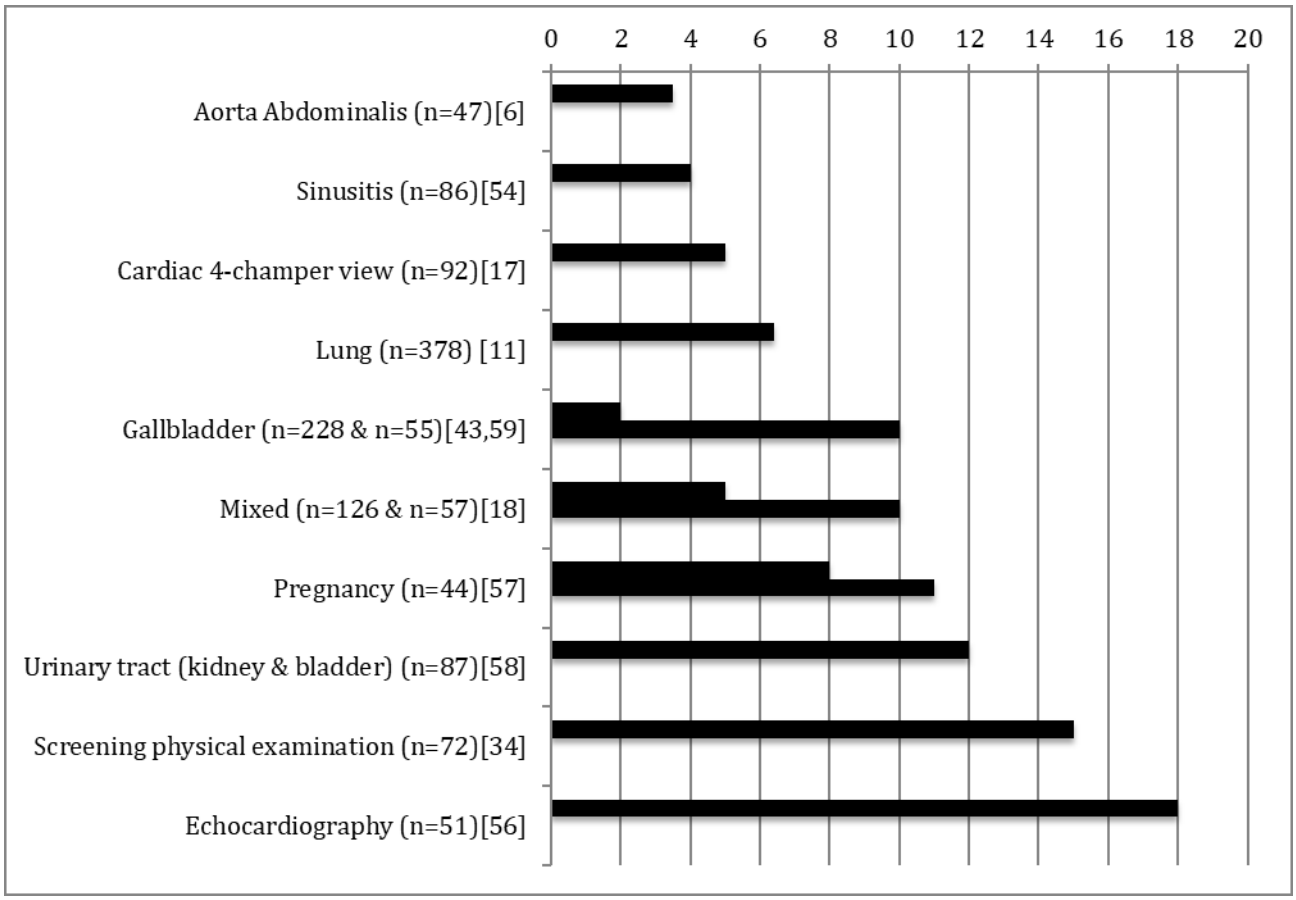
Some studies describe POC-US use for screening purposes, e.g. scanning for an aortic aneurism[6,32] or a general health screening.[34,44] In a German survey GPs reported finding 67 % of abdominal aortic aneurisms as incidental findings during other investigations [10] . We do not know the number of incidental

findings among Danish GPs who scan or if the Danish GPs extend their POC-US examination to opportunistic screening.

Time consumption:

In some studies the time consumption of POC-US was found to be no more than 10 minutes although POC-US performed for general screening or echocardiography was more time consuming (Figure 1)

Figure 1



The effect on the diagnostic process

Many articles describing the use of POC-US in general practice state the indication and the findings, but details regarding the diagnostic process are missing, e.g. whether POC-US actually changes the presumptive diagnosis and how much emphasis POC-US adds to the diagnostic process?

A randomized controlled trial [4] examined patients with respiratory symptoms, who were admitted to the hospital. In this study, the number of correct diagnoses, increased for patients, who were examined with POC-US as an additional test. However, patients in a hospital setting differ from the patient population in general practice, with more advanced or complicated disease.

In an American survey from 2014 [13], military family physicians were introduced to a pocket ultrasound device and trained in broad use of POC-US. Afterwards they were asked about their experiences. 60% felt that POC-US improved their ability to make an accurate diagnosis and 67% found that POC-US was timesaving in the diagnostic process. Furthermore a survey from rural Canada in 2013 [15] found that 78 %

of the GPs thought the result of POC-US would change their clinical decision and 72 % stated that it would improve patient care.

The effect on the plan and treatment of patients

POC-US may allow more rapid or correct diagnosis and in some cases direct referral to a relevant department or eliminate the need for referral. However, applying POC-US in general practice inevitably entails a certain amount of overdiagnosis, incidental findings and possible misdiagnoses.

A Norwegian study [18] describes specifically how the use of POC-US in 200 patients in general practice changed the treatment and plan for 90 patients as 35 referrals for POC-US, 40 referrals for a specialist opinion, and 15 referrals for procedures were avoided.

The number of misdiagnoses are only disclosed to a limited extent in the published studies [18,26,29,31,34,35,44,46,53] . In an Italian study [5], POC-US was used to rule-in or rule-out diagnostic hypotheses, and 4,9 % of findings in POC-US were later classified as false negative. Overdiagnosis was not addressed in the published studies, but incidental findings were described in several studies [34,35,44,46,56,58,59] .

Future GPs will be familiar with the technology as POC-US is part of the medical education at the university and the postgraduate specialization to become a general practitioner. To gain the benefits and avoid unnecessary harm by the utilization of POC-US in general practice it is crucial that the use of POC-US in a general practice setting is properly evaluated.

Objective:

The aim of this study is to describe: How general practitioners use POC-US in their daily practice, how POC-US influences the diagnostic process, and how POC-US affects the treatment of the patients.

The Use of POC-US will be explored through *indication, frequency, time consumption, modification, and findings* in order to describe:

- Which organs the GPs scan, when using POC-US?
- Which tentative diagnoses entail the use of POC-US?
- If GPs intend to rule-in/rule-out or explore, when using POC-US?
- How often the GPs use POC-US?
- How often are the GPs able to produce POC-US pictures of relevant structures?
- How much time POC-US adds to the consultation?
- How often a difference in what the GP intends to scan and what POC-US is actually used for occurs (modification of the performed POC-US)?
- How often POC-US leads to a specific finding?

The influences of the diagnostic process will be explored through change in the tentative diagnosis and change in the GP's confidence in the tentative diagnosis. We aim to describe:

- If POC-US changes the patient's tentative diagnosis
- If POC-US increases the GP's confidence in the tentative diagnosis

- The relationship between the GP's expression of confidence and change in the number of tentative diagnoses
- The relationship between change from symptom diagnoses to disease diagnoses and the GP's expression of confidence in the tentative diagnosis
- The relationship between specific organs scanned and the GP's expression of confidence in the tentative diagnosis

The effects on the treatment of patients will be explored through changes in the plan or treatment for the patient. We aim to describe:

- If POC-US changes the GP's plan for the patient
- If POC-US changes the treatment for the patient
- The relationship between findings and change in the plan or treatment for the patient.

Trial design:

A prospective observational cohort study

Study setting:

The study will take place in 20 different general practices in Denmark where the GPs use POC-US. The study is coordinated from the Research Unit for General Practice in Aalborg that also has a list of the participating study sites (GP clinics) and hosts data assessed from the clinics and patients.

Eligibility criteria

Participating doctors:

The participating GP practices will be selected purposively aiming at a difference in organisation, geography, and equipment. GPs will be selected to vary in experience both regarding seniority as GPs and experience of using POC-US. Thus we will include partnerships and solo practices, urban and rural practices as well as practices with variable number of probes and type of ultrasound scanner.

The GPs must fulfil the following criteria:

Inclusion criteria:

1. Broad use of POC-US (minimum two anatomical areas evaluated by OSAUS at baseline)
2. Working week of minimum four days
3. A minimum of 1400 patients listed
4. A minimum of two scanning probes
5. Previous participation in formal education in the use of POC-US
6. Minimum six months experience with POC-US in general practice.
7. Estimated use of POC-US on a daily basis (average)

Exclusion criteria:

1. Ultrasound device more than 10 years old

2. Conflict of interest, e.g. if the GP is part of the research group or if the GP has/had direct financial interest in selling US devices.
3. If less than five patients have been enrolled.

Participating patients:

Patients must provide written, informed consent before any study procedures occur (see Appendix 1 for sample Informed Consent Form). Only patients assigned to the GP's practice can participate in the study.

Interventions

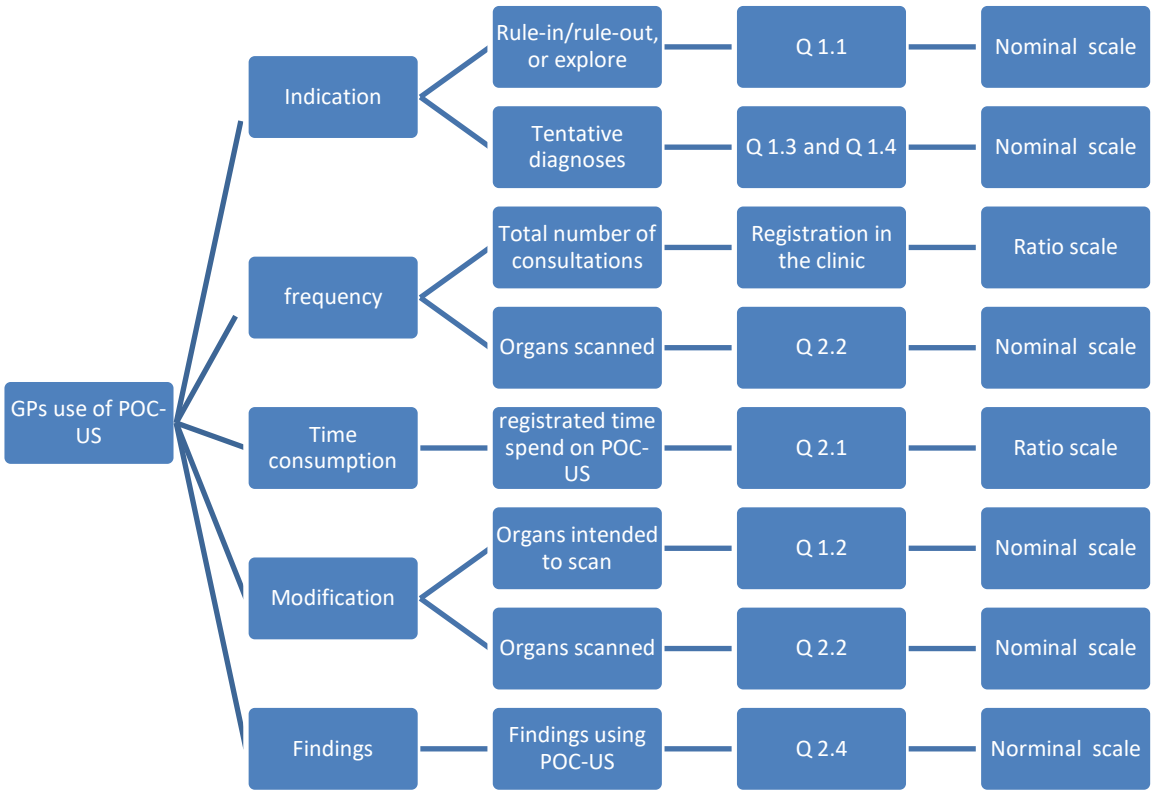
There is no intervention in this study since the GPs are already using POC-US in their examination of patients. The registration for this study will reflect the GPs' normal daily use of POC-US not adding more examinations or in other ways influencing the treatment of patients.

If patients are re-scanned on a later occasion, only the primary scan will be included in the analysis. However, any additional scans or procedures are part of the six months follow-up study (not described in detail here).

Outcomes

How general practitioners use POC-US in their daily practice:

The use of POC-US will be examined through the domains *indication, frequency, time consumption, modification, and findings.*



Indication:

The GP's indication for using POC-US will be described through the frequencies of the GP's intention to *rule-in/ rule-out, or explore* when using POC-US (Q1.1). This binominal distribution will tell us whether the GP has a predefined condition to be confirmed or dismissed by POC-US (rule-in or -out) or if POC-US is used to explore a symptom. The indication will also be described through frequencies of the tentative diagnoses (Q 1.3 and Q1.4) that entail the use of POC-US.

Frequency:

How frequently POC-US is used will be described as the percentage of the GP's consultations, where POC-US is used in the study period. Each participant will provide information on the total number of face-to-face consultations she or he has had during the study period, not including planned preventive consultations or home visits. The frequency of the different POC-US examinations will be summarized in relation to the organs scanned (Q 2.2). The performed POC-US 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 POC-US and from pilot testing. The GPs can choose to write in free text if organs are missing from the list.

Time consumption:

The GPs will measure the time used for the POC-US 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 (Q2.1) will be described in minutes for each type of POC-US examination (Q2.2).

Modification:

By the before and after registration of the organs intended to scan (Q 1.2) and the organ actually scanned (Q 2.2), the extent of modification of POC-US to include e.g. opportunistic screening, can be estimated. The modification of the performed POC-US will be described in frequencies of POC-US examinations that are reduced, expanded or unchanged.

Findings:

The findings in POC-US are measured through the categorial variables *certain positive findings, un*certain *positive findings, certain negative findings, uncertain negative findings, and incidental findings* (Q2.4). The findings will be described in frequencies and we will also describe the correlation between certain findings and change in treatment and plan for the patient.

How POC-US influences the diagnostic process:

Change in diagnose:

The GPs are asked to declare the tentative diagnoses as one main tentative diagnosis (Q1.3) and other possible diagnoses (Q1.4) before the use of POC-US. After the use of POC-US the GPs will be shown their "Before-US" tentative diagnoses (Q1.3and Q1.4) and asked if these diagnoses have changed (Q2.5). If the diagnoses have changed, they will be asked to specify this (Q 2.6 and Q2.7).

The tentative diagnoses are registered as ICPC-2 codes in the questionnaire. The ICPC-2 code system is a familiar tool for the GPs and an overview of all ICPC-2 codes will be provided as a pdf file. Although ICPC-2 codes cover both symptom diagnoses and disease diagnoses [62,63], they do not cover all clinical conditions. Thus it is possible that the patient's tentative diagnosis changes after POC-US, but the ICPC-2 code remains the same. Q2.5 is designed to clarify this issue.

Change in the tentative diagnoses is measured in the frequency of GPs' declaration of change and in 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 tentative diagnosis after US (Q1.3 and Q 2.6)
- Change in all possible ICPC-2 tentative diagnoses after (Q1.4 and Q2.7) the use of POC-US
- Change in the total number of tentative diagnoses …..(Q1.3,Q1.4, Q2.6 and Q2.7)
- Change from symptom diagnosis (ICPC 2 1-29) to disease diagnosis (ICPC 2 70-99) after POC-US (Q1.3,Q1.4, Q2.6 and Q2.7)

Change in confidence:

The GPs are asked to register any change in their confidence in the tentative diagnoses after the use of POC-US (Q2.8) by choosing one of the following variables on an ordinal scale: *Increased confidence, more confident, unchanged confidence, less confident, reduced confidence.*

To test the reliability of the GPs' declaration of confidence (Q2.8), we will examine if an increased confidence is correlated to specific organs scanned (Q2.2), a reduction in the total number of diagnoses (Q1.3, Q1.4, Q2.6 and Q2.7), or a change from symptom diagnosis to disease diagnosis (Q1.3,Q1.4, Q2.6 and Q2.7).

How POC-US affects the treatment of the patients:

Change in the plan for the patient

The GPs register their plan for the patient by choosing one or more of the following categorical variables before (Q1.5) 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, 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 (Q2.9). If the plan has changed, the GP is asked to specify (Q3.0).

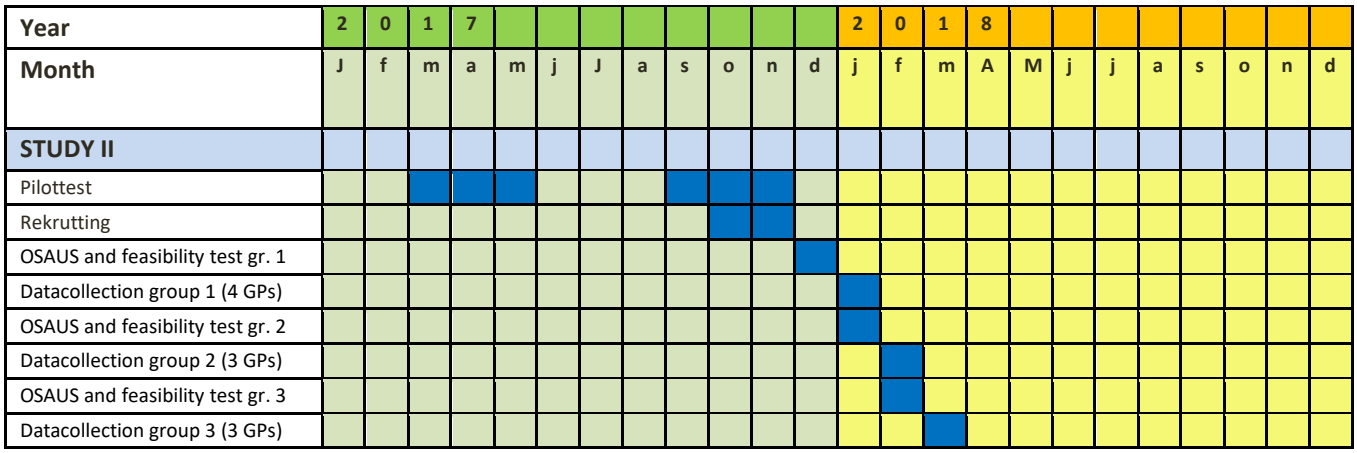
Change in the plan for the patient is defined as the frequency of declared change and elaborated on in this before and after registration from one possible answer to another, or change in the number of possible answers.

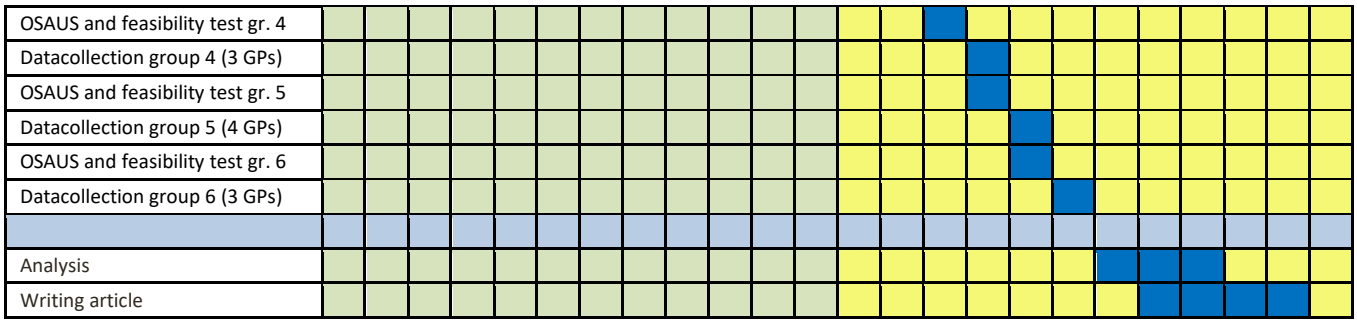
Change in the treatment for the patient

The GPs register their initiated treatment before POC-US (Q1.6) by choosing one or more of the following categorical variables: *Referral for treatment in the secondary sector, medication, other treatment, no treatment, other.* After using POC-US the GP is shown the "before POC-US planned treatment for the patient" and asked if this planned treatment has changed (Q3.1). If the planned treatment has changed, the GP is asked to specify (Q3.2)

Change in the initiated treatment of patients is defined as the frequency of declared change and elaborated on in this before and after registration from one possible answer to another, or in the number of possible answers.

Participant timeline





Sample size

The overall aim of this study is to describe how POC-US is used in Danish general practice. Based on a pilot questionnaire (unpublished data), we estimate that there are around 75 GPs in Denmark, who use POC-US. We find it realistic to include 20 GPs in this study. This sample size will enable us to have some variation (geographical, experience, etc) among the included GPs.

We estimate from our own experience and from talks with GPs, who scan, that the GPs will use POC-US 2-3 times a day, and assuming a participation rate of 80%, we will therefore have 640-960 US scan during the study period of one month. This number of scans is expected to be sufficient to give a valid statistical description of e.g. frequencies of organs scanned (see table 1) and other outcomes. Additionally, it is a sufficiently large number of scans to enable an evaluation of safety when we later on make the six months follow-up. We hope to maintain the GPs' dedication to the project by the relative short study period (one month).

Recruitment

Participating GPs:

GPs using POC-US will be recruited through the continuous medical education small-groups program , US networks, conferences, through teaching sessions, and through contacts via the Danish general practice research units. Interested GPs will be asked to register and answer a questionnaire including background information. The participating GPs will be selected randomly among these registrations after considering in- and exclusion criteria.

Baseline questions to describe the participating GPs (BQ):

Question number	Question	Catagory
BQ 1.1	How old are you?	Age
BQ 1.2	Are you a woman/man?	Gender
BQ 1.3	How many years have you been a GP?	Experience
BQ 1.4	Which year did you graduate as a doctor?	Experience
BQ 1.5	How long have you been using ultrasound?	Experience
	How often do you use ultrasound?	Frequency
BQ 1.6	Would you characterize your practice as a predominantly rural, urban or mixed	Location

BQ 1.7	How is your practice organized? (solo, partnership, collaboration)	Organization
BQ 1.8	How many patients are assigned to your practice?	Organization
	How many days a week do you do clinical work?	Organization
BQ 1.9	In which region do you practice?	Location
BQ 2.0	What is the approximate distance from your practice to the nearest radiology department where US can be performed?	Location
BQ 2.1	What kind of US device (name, model, year) and probes do you have?	Equipment
BQ 2.2	What kind of ultrasound education/training did you receive?	Experience
BQ 2.3	How often do you use ultrasound?	use
BQ 2.4	Do you have a conflict of interest, participating in this study?	COI

Base-line assessment of GPs

We will evaluate the GPs' technical skills at baseline. After inclusion, each participating GP will be asked to perform POC-US in a standardized setting and reviewed by an external reviewer (radiologist) using the standardized protocol, OSAUS[60]. This protocol is used for the certification of GPs in POC-US at the Center of Clinical Ultrasound at Aarhus University Hospital [61] . This rated evaluation will serve as background information on the participating GPs. It will take place at different locations and if possible on the GPs own US device. There will be no more than three months between evaluation and data-collection for each GP. The GPs will not be informed about their rated evaluation score until after the study.

Participating Patients:

All patients who consult the participating GP for conditions relevant for a POC-US examination will be offered to participate in the study. Patients are excluded if they do not wish to participate or if they are not able to give an informed consent.

Data collection

Normally a consultation in general practice takes 5-15 minutes. POC-US is expected to add another 10 minutes. During this study the GPs will be asked to measure the time used for POC-US examination and fill out a questionnaire before and after the use of POC-US which adds approximately 10 minutes to the consultation. The GPs will be financially compensated for the time used to register data for the study. The GPs will also be asked to give information about the total number of consultations in the clinic in the study period.

Developing the registration tool:

We will develop a registration tool based on knowledge from the literature, dialogue with the DSAM US group and an interview study. The registration tool will be developed as a questionnaire to be used before and after the GP uses POC-US in the consultation. The questionnaire will include a time log to ensure the before and after registration. We will perform several pilot tests both in the research group and GPs using POC-US in order to ensure comprehension, feasibility and compliance.

- Step 1: Developing a preliminary registration tool/questionnaire based on literature, discussions in the research group and individual interviews with GPs.
- Step 2: The pilot test will consist of consecutive rounds of GPs testing the questionnaire. In each round five GPs who use POC-US will be asked to use the questionnaire in relation to three

consultations. They will be asked to comment and declare any difficulties on each question and part of the questionnaire. After each round adaptions be will made by the research team until the questionnaires are completed without difficulties.

- Step 3: Data from step 2 will be analyzed and final adaptions will follow.

Ensuring feasibility:

In order to ensure comprehension and validity of the registration tool, the principal investigator will visit each participating GP 1-2weeks before the data collection starts. At this visit the GP will be asked to fill out the registration tool before and after using POC-US in a patient. After each registration the principal investigator will interview the GP asking the same questions as covered by the registration tool. The GP will then answer in his/her own words. The principal investigator will then answer the registration tool based on the GPs explanations. The two questionnaires are then compared and any miscomprehensions or difficulties resolved. At the same time feasibility is tested.

Registration tool:

The GPs will be asked to access a questionnaire in the online database SurveyXact each time they use their ultrasound device 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 each participating GP. A key file, connecting each participating GP with the respondent link in Surveyxact (link), will be safely stored at the Research Unit for General Practice in Aalborg.
The GPs will give each patient a unique ID-number (PQ 1.2). A Key file connecting this ID-number and the patients CPR-number will be safely stored at the GP's clinic.

Questions BEFORE the use of POC-US:

Question number	Question	Possible answers
PQ 1.1	GP ID number	GPxx
PQ 1.2	Patient ID number	Pxxx
PQ 1.3	Date	Dxxxxxxxx
PQ 1.4	Patient gender	Male/female
PQ 1.5	Patient Age	xxx years
Q 1.1	What is the main reason to use POC-US in this patient?	Rule-in/Rule-out Explore
Q 1.2	Which organs/positions do you expect to scan?	Organs on list
Q 1.3	What is the main tentative diagnosis for this patient?	ICPC2 codes
Q 1.4	Are there any other possible tentative diagnoses in this case?	ICPC2 codes
Q 1.5	What is your overall plan for this patient?	Acute admission to hospital

		Subacute referral to hospital Elective referral hospital Subacute referral to specialist Elective referral to specialist Referral to radiology Other referral e.g. physiotherapist Follow-up in the clinic No plan for follow-up Other
Q 1.6	Which treatment will you initiate at this stage?	Medication I will refer for treatment I will initiate other treatment None Other

Questions AFTER the use of POC-US:

Question number	**Question**	**Possible answers**
Q 2.1	How much time did you use on the POC-US examination?	Minutes
Q 2.2	Which organs/positions did you scan?	Organs in drop-down menu
Q 2.3	Were you able to produce ultrasound images of the relevant structures of (inserted text) ?	Yes No – why not?
Q 2.4	What did you find?	Certain positive findings Uncertain positive findings Certain negative findings Uncertain negative findings Incidental findings – please specify in free text
Q 2.5	Before POC-US you registered these tentative diagnoses (inserted text) Have your tentative diagnoses changed?	Yes, the diagnoses have changed but the ICPC2 codes

		are the same Yes, the diagnoses have changed and the ICPC2 codes have also changed No*
Q 2.6	What is the tentative diagnosis for this patient now?	ICPC2 codes
Q 2.7	Are there any other possible tentative diagnoses for this patient (please specify)?	ICPC2 codes
Q 2.8	How is your confidence in your main tentative diagnosis, after you have used POC-US?	Highly increased confidence More confidence unchanged confidence Less confidence Highly reduced confidence.
Q 2.9	Before POC-US you registered this plan (inserted text) for the patient. Has your overall plan changed?	Yes No**
Q 3.0	What is your overall plan for this patient, now?	Acute admission to hospital Subacute referral to hospital Elective referral hospital Subacute referral to specialist Elective referral to specialist Referral to radiology Other referral e.g. physiotherapist Follow-up in the clinic No plan for follow-up Other
Q 3.1	Before POC-US you registered this treatment (inserted text) for the patient. Has your initiated treatment for this patient changed?	Yes No*
Q 3.2	Which treatment will you initiate at this stage?	Medication I will refer for treatment I will initiate other treatment None Other

* Move on to Q2.8

** Move on to Q3.1

Time-log

We will register date and time, when the GP accesses the questionnaire and finishes the final question. Furthermore, we will have a java script on a page between the ”before” and the “after” questions, this java script will create a variable with the exact time between “before” and “after” questions.

If GPs use less than e.g. 1 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 (Q1.1 – Q1.6).

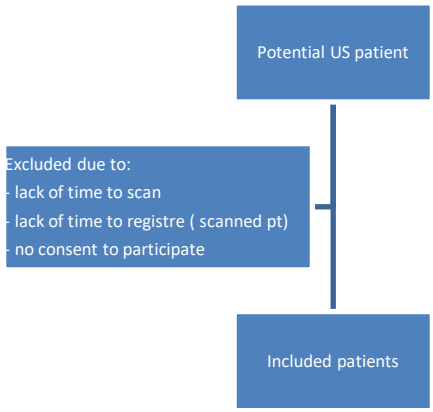
Patient experience:

After the consultation, patients will be asked to complete a questionnaire about their experience with POC-US in the consultation. This questionnaire will be described in detail in a separate protocol.

Retention

Participant Retention

Since the registration in this study is expected to add approximately extra 10 minutes to the consultation, the participating GPs will be asked to allocate time, in their daily time schedule, during the study period.



The GPs will be asked to register the following information on patients, who were eligible for the study, but not included due to e.g. time pressure: *age, gender, indication, organs intended to scan, tentative diagnosis and reason for exclusion.*
The Research group will send weekly updates to the participating GPs to maintain their interest in the project, to remind them of including patients, when they use POC-US, and to address any difficulties in the procedures. The Research group will also contact GPs who fail to register patients in SurveyXact in order to solve any difficulties.

The participating GPs will only receive financial compensation for patients in whom the registration in SurveyXact is complete.

Participant Withdrawal

Participating GPs and patients may withdraw from the study for any reason and at any time. The investigator may also withdraw participating GPs from the study if they are unwilling or unable to comply with required study procedures.

If the GP has included less than five patients (10%), the GP and the patients will be excluded from the study. The GPs will still receive financial compensations for the patients if the registration is complete. We will then try to include another GP for the study.

Follow-up

The GPs will be asked to save patient information on the included patients (Key file) in order to identify the patient for an additional follow-up after six months (described in a separate protocol).

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 passwords. The patient key file and consent forms will be saved locked up 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 saved locked up at the Research Unit of General Practice in Aalborg and Department of Clinical Medicine, Aalborg University, Fyrkildevej 7,1, 9220 Aalborg Ø.

The Research Unit for General Practice in Aalborg is the Data Controller. Each participating GP will be data processor and can only process data pursuant to an agreement with the data controller. A data processor agreement will be made between the Research Unit for General Practice in Aalborg and each participating GP, between the Research Unit for General Practice in Aalborg and Aalborg University, and between Aalborg University and SurveyXact according to the Danish Data Protection Agency recommendations.

Statistics

We will use descriptive statistics. The registration tool will mainly collect data on nominal scales. However, *Confidence after POC-US* will be measured on an ordinal scale and *Time consumption* and *patient age* on a ratio scale.

The categorical variables will be described using absolute frequencies tables and chi-square or Fishers exact test to test the relationship between variables. Continuous variables will be described with median and interquartile range and if *Time consumption* is normally distributed it will be reported with means and either a standard deviation or a 95% confidence interval of the mean; if not normally distributed with a median and interquartile range.
The relationship between *Confidence after POC-US* and *number of possible tentative diagnoses* will be described using a scatter plot.
A prospective statistical analysis plan will be developed before datacollection begins.

Data monitoring
During the study period the research team will follow the inclusion of patients by each GP and make contact to the GPs who fail to include patients in order to help with any difficulties.

Harms
We will register all adverse events occurring during the study and follow-up period.

Auditing
During the study period the principal investigator will monitor the registered data in SurveyXact in order to contact the GP if any difficulties occur.

Research ethics approval
The studies will be notified to the Danish Data Protection Agency, the Committee of Multipractice Studies in General Practice and will not commence before approval.
Since the study is an observational study and does not include any intervention, approval by the Danish National Committee on Health Research Ethics is not considered to be needed, but we will apply to be sure.

Protocol amendments
Will be declared and all editions and changes of the protocol will be saved.

Consent or assent
Each participating GP will collect data for all POC-US examinations conducted during a one month period. Prior to participation patients will receive written and oral information and a written consent to participate will be obtained by the participating GP. The consent forms will be saved in the GP's office.
The participating GPs will also give an informed consent before participating in the study.
Before analyzing the data the principal investigator will ensure that there are consent forms on all participating patients and GPs.

Confidentiality
All participating GPs have signed a confidentiality agreement.

Declaration of interest
All participating GPs and investigators will sign a conflict of interest form.

Access to data
Only the Research team will have access to data.

The key files linking the patient ID and the CPR-number will be stored under lock in the GPs' clinics. Only the participating GP will have access to the key file. The data will be saved at a server in SurveyXact or

Aalborg University. Only the research team (MBJ and CAA) will have access to this data using two unique passwords.

Dissimination polity

Manuscript 1:

Title: The use of ultrasound in the examination of patients in general practice.
Authors: Camilla Aakjær Andersen, Ole Graumann, Annette Davidsen, John Brodersen, and Martin Bach Jensen
Expected Journal: International peer-reviewed journal
Expected Time of Submission: August 2019

Manuscript 2:

Title: Point-of-Care Ultrasounds impact on the diagnostic process in general practice.
Authors: Camilla Aakjær Andersen, Ole Graumann, Annette Davidsen, John Brodersen, and Martin Bach Jensen
Expected Journal: International peer-reviewed journal
Expected Time of Submission: Oktober 2019

The knowledge of this study will be disseminated through conferences, research networks, and papers published in peer reviewed journals. It is expected that the audit on the patient pathway after six month follow-up also will be presented in an article.

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