How Patients Experience the use of Point-of-Care Ultrasounds in General Practice.

Protocol version: 29-01-2018

Registration:

The study will be registered at clinicaltrials.org. The protocol was uploaded to clinicaltrials.gov on 08-01-2018. No changes in the content of the protocol, have been made since.

Part of the cohort study: How Point-of-Care Ultrasound (POC-US) Affects the Diagnostic Process in General Practice. A prospective follow-up study. (Clinical trials registration number: NCT03375333)

Funding:

The Research Unit for General Practice in Aalborg supports the study. Additionally, various foundations will be applied for support, but they will have no influence on the study design, analysis of data or the reporting of results.

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Introduction:

There are only few articles describing the use of POC-US in general practice.[5,6, 10-59] Most of these 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. There are no studies describing the use of POC-US in Danish general practice and only a few studies describe the patient perspective. In these studies, it seems that the use of POC-US in general practice is in line with patient preferences, however these studies were performed in rural areas, where access to specialists and ultrasound examinations were hours away, which is never the case in Denmark. Furthermore one study described that 29%.of patients felt that the GP were putting to must emphasis on technology in the consultation and 19% found ultrasound disrupting for the patient-doctor relationship. [18]

In a qualitative interview study with Danish general practitioners a range of motivating factors for using POC-US concerned the patient perspective. The GPs felt that they were improving patient care by using POC-US as part of their examination of patients and that the patients appreciated the use of POC-US. In this present study we wish to explore the GPs believes, about how POC-US in general practice is experienced by the patients, by asking the patients.

Objective:

Primarily we seek to explore to what extend:

- patients feel informed about the use of POC-USin general practice
- patients experience that POC-US has an influence on the consultation with the GP.
- patients experience POC-US influences the doctor-patient relationship.
- patients feel diagnostic reassured after the POC-US examination?
- do patients feel that POC-US is improving care?
- are patients satisfied with POC-US in the GP's office?

Secondary we seek to test the association between GPs declared confidence in the tentative diagnosis after using POC-US in the consultation and patients experiences with POC-US in the consultation.

- How is GPs level of confidence in the diagnosis associated with patients' feeling of reassurance (assessed immediately after the POC-US examination)?
- How is GPs level of confidence in the diagnosis associated with patients' experience of improvement of care?

Trial design:

Cross-sectional study

Study setting:

The study will take place in 20 different general practices in Denmark where the GPs use POC-US. The study is part of a follow-up study designed to explore how POC-US affects the diagnostic process in general practice.

The participating GPs will try to include all patients were they use POC-US in the consultation. After the consultation patients will be asked to fill out a questionnaire about their experience with POC-US in the consultation. The GPs will provide the patients with a unique ID-number and a link to an online questionnaire on the SurveyXact server. The patients will then access the online questionnaire using this ID-number either through Ipads in the clinic or at home using their own computer, tablet or phone. If the patient feels uncomfortable using an online questionnaire, a paper edition will be in provided by the GP including a labelled envelope.

Baseline information (BQGP) regarding the participating GPs will be provided through the original study. Baseline questions about the patients (BQP) will be part of the patient-questionnaire following the consultation.

Baseline questions to describe the participating GPs (BQGP)

Question number	Question	Catagory
BQGP 1.1	How old are you?	Age
BQGP 1.2	Are you a woman/man?	Gender
BQGP 1.3	How many years have you been a GP?	Experience
BQGP 1.4	Which year did you graduate as a doctor?	Experience
BQGP 1.5	How long have you been using ultrasound?	Experience
BQGP 1.6	Would you characterize your practice as a predominantly rural, urban or mixed	Location
BQGP 1.7	How is your practice organized? (solo, partnership, collaboration)	Organization
BQGP 1.8	In which region do you practice?	Location
BQGP 1.9	What is the approximate distance from your practice to the nearest radiology department where US can be performed?	Location
BQGP 2.0	What kind of US device (name, model, year) and probes do you have?	Equipment
BQGP 2.1	What kind of ultrasound education/training did you receive?	Experience

Baseline questions about the participating patients (BQP)

Question number	Question	Catagory
BQP 1.1	Are you a woman/man?	Gender
BQP 1.2	How old are you?	Age
BQP 1.3	Have you been ultrasound scanned in this clinic before?	Previous experience
BQP 1.4	Employment	Socioeconomic background
BQP 1.5	Level of education	Socioeconomic background
BQP 1.6	Level of higher education	Socioeconomic background

Eligibility criteria

Patients must provide written, informed consent before any study procedures occur (see Appendix 1 for sample Informed Consent Form). Only patients assigned to the GPs 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 in this study will reflect their normal daily use of POC-US not adding more examinations or in other ways influence on the treatment of patients.

Outcomes

The items in this questionnaire are generated from a qualitative interview study with GPs working in general practice and using POC-US. The items are the GPs expressed believes and concerns about how POC-US was experienced by their patients.

Domain	Item	Questions
Information	Information on the purpose	Were you informed about the purpose of the ultrasound examination?
	Information on the limitations	Were you informed about the difference between a specialist ultrasound and a GP ultrasound?
	Information about the findings	Were you informed about the result of the ultrasound examination?
Consultation	Natural part of the consultation	Did you think the ultrasound examination was a natural part of the consultation?
	Disruptive in the consultation	Did you think the ultrasound examination was disruptive in the consultation?
	Influence on the relationship during the examination	Did the ultrasound examination influence the relationship between the GP and you?
	Importance	Do you think ultrasound made a difference in the consultation?
Reassurance	Thoroughly examined	Do you feel more thoroughly examined after the ultrasound examination?
	Explanation	Do you have a better understanding of your health problem after the ultrasound examination?
	Sense of security	Do you feel more at ease after the ultrasound examination?
	Sense of confidence	Has your confidence in the GPs diagnosis changed after the ultrasound examination?
	Feeling of being taken seriously	Has the ultrasound examination changed your feeling of being taken seriously?
Patient satisfaction	Overall evaluation	Was your overall experience with ultrasound in the GP's office positive or negative?
	Recommendation to others	Would you recommend ultrasound in the GPs office to others?
	Service improvement	Do you think ultrasound is a service improvement in the GP's office?
	Quality improvement	Do you think ultrasound is a quality improvement

		in the GP's office?

Participant timeline

Year	2017						2018					
Month	July	Aug	Sep	Oct	Now	Dec	Jan	Feb	Mar	Apr	May	June
Activity												
Pilot												
Data collection												

Sample size

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 include 640-960 patients during the study period of one month..

Recruitment

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 method

This questionnaire is developed through the following steps:

1. A first edition of the questionnaire is developed based on the results of a qualitative interview study with Danish GPs on their experiences on how ultrasound can be used in general practice. This study included both users and non-users of POC-US and the GPs reported how they experienced patient attitudes and reactions to POC-US in general practice. The quotations from the interviews were included as items in a conceptual model with domains covering the central aspects of the GP's impressions of patients' experiences of POC-US in general practice.
2. To test face validity, comprehension and wording, pilot tests will be done with laypeople and patients, who have not been ultrasound scanned, using the "think-aloud" technique and cognitive interviewing. The pilot-tests are done in two geographical-separated clinics including five patients in each clinic. Adaptions and rephrasing will follow after comparing the results.
3. A validation test will include presenting the rephrased questions to 5 GPs, who use POC-US, and asking them to compare the questions to the original items from the qualitative interviews. Adaptions will follow.
4. A final pilot-test will include interviews with patients in two new clinics using the "Think-aloud" technique. In this pilot-test the patients are presented to both a paper-version and an online-

version of the questionnaire, to test functionality and feasibility. Pilot-tests and adaptions will continue until the questionnaire is completed without difficulties.

Retention

Participant Retention

We will ask the GPs to register not-included patients, in whom POC-US was used during the study period, on a separate form and to declare the reason for the failed inclusion of the patient.
The Research group will send weekly updates to the participating GPs to maintain their interest in the project, to remind them to include patients when they use POC-US, and to address any difficulties in the procedures.

Participant Withdrawal

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

Data management

Data will be saved electronically in the SurveyXact server and on a server at Aalborg University and will only be accessed by the research group using passwords.
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 agreements 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.
The Key files identifying the patients will be safely stored at the GPs office and the research group will not have access to this information during the study.

Statistics

The questionnaire data will be collected on an ordinal scale and reported descriptively using frequencies. To test if the observed frequencies are statistical significant, we will use Chi squared test or fishers exact test. A p-value of 0.05 will be considered statistical significant. The association between the GPs reported *confidence in the tentative diagnosis* on an ordinal scale from decreased confidence to increased confidence, and *patients reported experience of POC-US in the consultation* will tested using Goodman and Kruskal's gamma.

Data monitoring

During the study period the research team will be able to observe if the GPs include patients in the study and make contact to the GPs who fail to include patients in order to help out with any difficulties.

Harms

We will register all adverse events occurring during the study.

Research ethics approval
The studies will be reported to the Danish Data Protection Agency, the Committee of Multipractice Studies in General Practice and will not commence before approval.

Concent or assent
Each participating GP will collect data for all conducted POC-US examinations in a one month period. Prior to participation, patients will receive written and oral information and a written consent to participate will be obtained.
If a GP or a patient wished to redraw their consent to participate in the study, the GP will contact the research team and the data will be deleted.

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

Confidentiality
All participating GPs have signed a confidentiality agreement.

Declaration of interest
None

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

The key files linking the patient ID and the social security number will be stored under lock in the GPs clinics. Only the participating GP will have access to the key file. The anonymized 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.

Dissemination polity

Manuscript 1:
Title: How patients experience the use of point-of-care ultrasound in general practice.
Authors: Camilla Aakjær Andersen, Torsten Rahbek Rudbæk, John Brodersen, and Martin Bach Jensen
Expected Journal: International peer-reviewed journal
Expected Time of Submission: Fall 2017

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