



Research Article

Feasibility and Utility of Point-Of-Care Ultrasound (POCUS) in Primary Care Practice. EKOAP Pilot Study

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Abstract

Objective: To evaluate the feasibility and utility of point-of-care ultrasound (POCUS) in primary care (PC) practice, considering use, findings and diagnostic coincidence. **Methodology:** Pilot study of a cross-sectional multicentre nature, registering ultrasounds (July 21-July 22) of six family doctors with experience in POCUS. **Variables:** age/sex, characteristics of ultrasounds (type, duration, location), diagnostic-therapeutic referrals/interventions, findings and diagnostic coincidence (five months of monitoring). **Analysis:** Statistical single-variate-inference, bivariate-association of variables, logistical regression (dependent variable: ultrasound alterations); 0.05 significance. Data exported from Excel to SPSS-25 for their analysis. **Results:** A total of 547 ultrasounds. Mean age 54.3 ± 18.8 years, 55% women. Different duration according to modality: abdominal/pelvic/urological (37.1% of the total) 13.9 ± 5.2 minutes, osteoarticular (25.8%) 11.8 ± 3.6 , soft tissue (20.7%) 8.7 ± 3.5 , $p < 0.001$; others: pulmonary, vascular, thyroids/neck, testicle/gynaecological. Scheduled 73.0% vs. 27.0% immediate (mainly pulmonary, 61.9%) and vascular, $p < 0.001$. With ultrasound alterations 65.1% (CI95% 61.9-68.9%) more frequent in osteoarticular 27.3%, soft tissue 21.2%, and urological 14.9%; associate with: modality (soft tissue OR with respect to abdominal/pelvic/urological of 19.9, CI95% 9.2-43.0; musculoskeletal OR 3.6, CI95% 2.2-6.1), $p < 0.001$; being male (OR 1.8, CI95% 1.2-2.8, $p = 0.008$); and age ≥ 80 years (OR 8.8, CI95% 3.2-24.1, $p < 0.001$). With no ultrasound diagnostic coincidence 5.7% (CI95% 3.8-7.7%), associated with requesting further tests/referrals; two cases of carcinoma referred despite absence of ultrasound findings. Drainage/infiltration in 15 cases. **Conclusions:** The POCUS is shown to be feasible/compatible with the PC practice (duration and modalities), useful (findings/diagnostic coincidence), safe (diagnostic coincidence/handling). The different care realities could limit the generalization of results, although it also reflects the versatility of the use of the POCUS; with need to explore/broaden its potential applicability.

Keywords: Primary care; Ultrasound; Qualitative research; Pilot study

Introduction

Ultrasound progressively constitutes another tool in the usual family doctor visit in Primary Care (PC) [1], and is found to be a useful and reliable technique that increases the diagnostic capacity and favors decision making efficiently in many clinical situations, reducing waiting time, costs, exposure to radiation and increasing the user's satisfaction [2,3]; to the point of being considered as the "visual stethoscope of the future" [4,5]. Thus, it is increasingly becoming a skill to acquire in the training of the doctors of this care level. The best and greater portability of equipment has contributed to its extension as a technique in family medicine and of other disciplines [6], although slowed fundamentally by the time that certain examinations require in practices already overloaded, and also by the scarcity of the equipment [7].

As a technique influenced by the experience and skill of the examiner, as well as by the prevalence of pathology in the care setting where it is carried out (very different in the PC from the radiology service), it is very dependent on the level where it is used and of the characteristics of the professional who conducts it. For this reason, in PC it is advisable to focus it and limit it according to the specific and selective clinical scenarios, according to the characteristics of the pathology and level of uncertainty, in order to improve its characteristics of diagnostic test; this selective focus targeting clinical scenarios that are presented, it is known as clinical ultrasound in the point of care or "bedside" (point-of-care ultrasound, POCUS) [6], which is characterized by focusing on a specific clinical question or associated intimately with the specific clinical situation, with brief examinations, of lesser complexity than an extended examination, and that provide information

immediately with a correct interpretation and non-complex training. Many of these examinations with limited training obtain a high diagnostic precision [2,8], with many values of sensitivity and specificity in common situations [8], and good diagnostic concordance between family doctors and radiological specialists [9].

There are many clinical scenarios where ultrasound constitutes a high-value test, complemented by the anamnesis and physical exploration [10]: hepatic, biliary, pancreas and spleen, large abdominal vessels, urological, neck, vascular, scrotal, osteoarticular, skin and soft tissue, emergency situations, basic echocardiography, pulmonary, ultrasound-guided procedures, emergencies [11].

However, to date and due to a progressive and relatively slow implementation in PC, there are hardly any quality studies in our environment that have analyzed the relationship between the ultrasound scans performed with the clinical benefits [2], also considering some disparity in the organization and structure of the healthcare organizations of the different health systems [12].

The objective of this study was to analyze, through a pilot study, the feasibility and clinical utility of the POCUS in PC, performed by experienced family doctors who already use it habitually in their practices, evaluating its applicability, clinical repercussion, diagnostic coincidence and safety.

Material and Methods

It deals with a cross-sectional multicenter descriptive pilot study that incorporates clinical monitoring for five months after the ultrasound examination. With the inclusion of the ultrasounds performed during one year (August 2021-July 2022) by family doctors of a working group on POCUS in PC, with experience and habitual usage of this technique.

Figure 1 shows the design and development of the study.

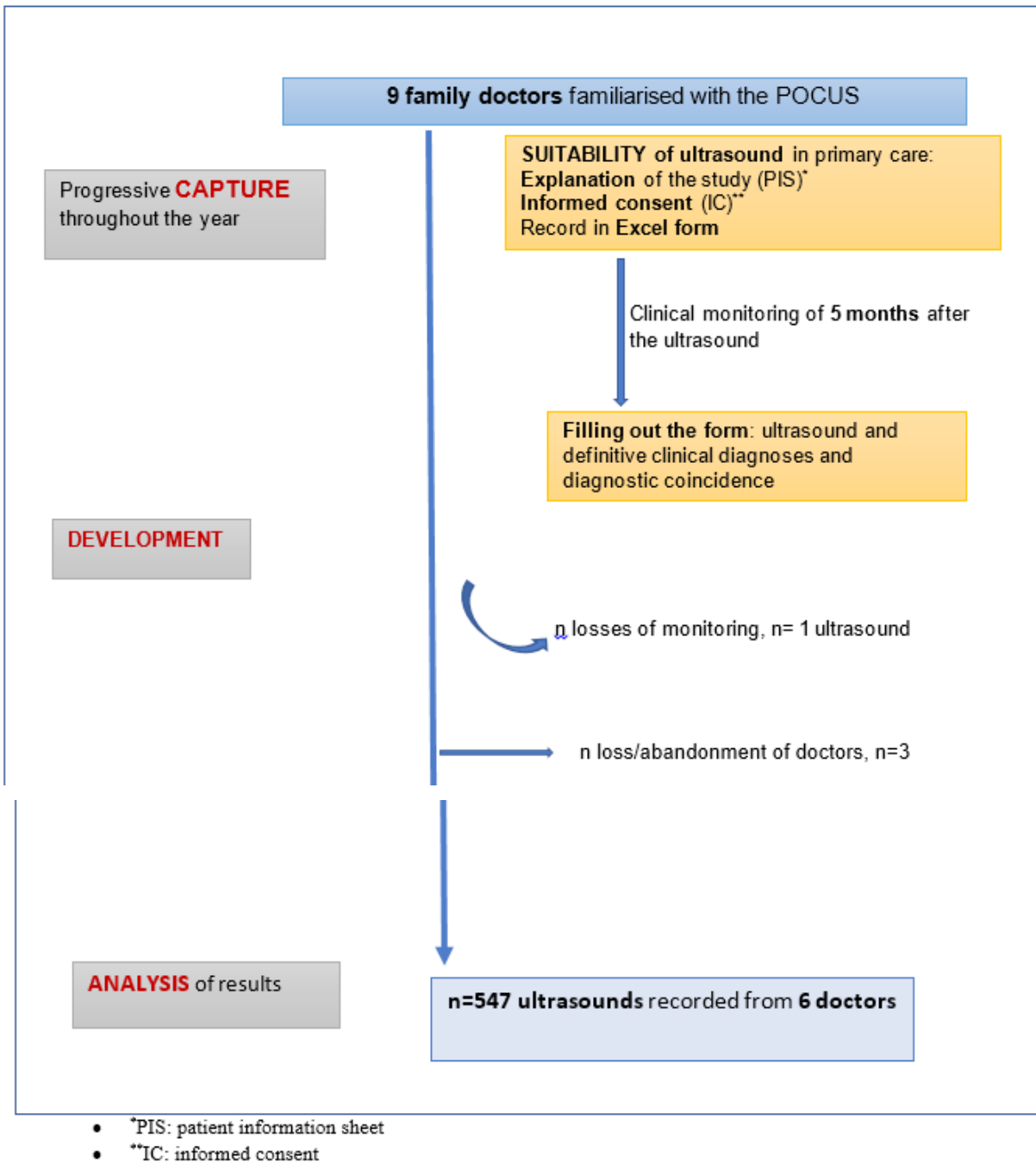


Figure 1: Design of the EKOAP study.

The study units consisted of all the ultrasounds performed and correctly registered during the year performed by the nine family doctors, with the reference population being the total ultrasounds performed in PC in the Autonomous Community. The refusal of the patient to have an ultrasound or that their data were used in this study were the criteria for exclusion and losses were considered to be ultrasounds if once indicated could not be done appropriately due to technical or patient's characteristics impeding the correct collaboration and participation (for example, cognitive or collaborative impairment, obesity, poor preparation, etc.), or that resulted not

to be of sufficient quality.

Although it was a pilot study, an estimate of the sample size was made. Supposing a proportion of 50% (most unfavorable situation), the realization of 2000 ultrasounds by PC doctors in the entire autonomous community in one year, with a confidence index of 95% and an error margin of 5%, 323 ultrasounds of the total sample were needed; increasing based on 5% of losses to 340 ultrasound scans.

The variables were differentiated by:

General descriptor variables of the professional/patient/study. Coding of the study, date, professional's name, patient's sex/age, ultrasound type-place (immediate/scheduled in visit, address, PC emergency –continuous point of care, CPC), reason for implementation, ultrasound modality and duration.

Procedures after ultrasound. New actions/referrals (yes/no), new ultrasound by the same professional, diagnostic-therapeutic instrumentalisation (infiltration, material extraction, o other), request for another diagnostic test (imaging by radiologist, endoscopies, blood analysis, others), referral to another specialist (specifying) or to hospital emergency unit.

Clinical and ultrasound diagnosis (detailed and grouped), initial and after five-month monitoring of evolution; also the diagnostic coincidence between both. To determine the diagnostic coincidence, the clinical monitoring was considered and records of five months with other tests or consultations with other specialists that may have occurred, the clinical stability in view of an initial test “without alterations”, and initial clear ultrasound diagnoses (for example, cholelithiasis, lipoma, pulmonary effusion, ...).

With respect to the ethical aspects, the patients received a patient information sheet (PIS) and signed the informed consent (IC). The study had the approval of the Research Ethics committee of Euskadi (CEIm-E). The patients from whom an ultrasound scan susceptible to forming part of this study was requested would not see their care process altered in any way from what they would have received had the study not been made; and they would receive the same care whether or not they decided to participate in the study. The forms are duly coded to keep patient records and data analysis anonymous.

Data analysis

A single-variate descriptive analysis was made, with percentages in the qualitative variables and mean or median, with respective dispersion statistics (Standard Deviation (SD), Interquartile Range (IQR)), statistical inference (CI: 95%) of the most relevant variables, and of association or contrast of hypothesis in the qualitative variables by means of the Chi-square test or Fisher's exact test in the bivariate analysis; and Student's t-test or the Mann-Whitney U test in quantitative variables. Furthermore, a logistical regression analysis was conducted between finding ultrasound alterations (dependent variable) and the general descriptor variables.

For the collection of data, different Excel forms were used by the organizing teams for each ultrasound modality, and stored and handled through the institution's computer cloud storage system. The data were later analyzed with the IBM-SPSS software, considering a significance level of $p=0.05$.

Results

A total of 547 ultrasounds were performed by six doctors, with a range of 12 to 185 ultrasounds per doctor. Only 1 was lost in which it was decided to perform an ultrasound for probable cervical adenopathy, but finally was not implemented as it coincided with the laboratory diagnosis of infectious mononucleosis. Table 1 shows the general variables related to the ultrasound scans and the professional actions following them. The other diagnostic tests conducted after the ultrasounds were mainly laboratory blood analyses (in 29 out of 34 cases). And the most frequent referrals to other specialists were to traumatology 24 (20.9%), urology 19 (16.5%), physical therapy 18 (15.6%), and surgery 17 (14.3%). Specifying the type of ultrasounds performed, the most frequent were: abdominal/abdominopelvic (136, 24.9% of the total), soft tissue (109, 19.9%), urological (67, 12.2%), musculoskeletal of the shoulder (61, 11.2%) or knee (46, 8.4), and pulmonary (43, 7.9%). The mean time in conducting the abdominal/pelvic/urological ultrasounds was 13.9 ± 5.2 min., the musculoskeletal 11.8 ± 3.6 , and those of the soft tissue 8.7 ± 3.5 , $p<0.001$.

Time in performing it, mean $\bar{x} \pm SD$ (max., min.)	11.9 \pm 4.6 (30, 3) minutes
Patient age, mean $\bar{x} \pm SD$ (max., min.)	54.3 \pm 18.8 (100, 5) years
0-14 years, n (%)	9 (1.6)
15-39 years	101 (18.5)
40-64 years	281 (51.4)
65-79 years	105 (19.2)
\geq 80 years	51 (9.3)
Sex females, n (%)	301 (55.0)
males	246 (45.0)
Ultrasound location In visit/scheduled, n (%)	399 (73.0)
immediate in visit	143 (26.0)
in the Continuous Point of Care (CPC, emergencies)	5 (1)
Ultrasound type/group abdominal/abdominopelvic/urological, n (%)	203 (37.1)
musculoskeletal	141 (25.8)
soft tissue	113 (20.7)
pulmonary	43 (7.8)
thyroids/neck	25 (4.6)
vascular-venous-lower limbs (LL)	12 (2.2)
testicular/gynaecological	9 (1.6)
cardiac	1 (0.2)
More actions after ultrasound (tests/referrals), n (%)	254 (46.4)
New ultrasound by us after ultrasound, n (%)	68 (12.4)
Other diagnostic test after ultrasound	145 (26.5)
Simple X-ray, n (%)	53 (36.6)
CT/NMR	28 (19.3)
ultrasound by radiologist	28 (19.3)
colonoscopy/gastroscopy	2 (1.4)
others	34 (23.4)

Drainage/infiltration/other technique after ultrasound, n (%)	15 (2.7)
Referral to specialist after ultrasound, n (%)	116 (21.2)
Referral to hospital emergency unit after ultrasound, n (%)	14 (2.5)

Table 1: Variables related to the ultrasounds and actions after its performance.

Table 2 shows the association of the ultrasound type/group with the general variables, actions after the test and existence of ultrasound findings.

Ultrasound type	Patient's age (years)		p value p¹	
abdominal/abdominopelvic/urological, <i>median (IQR)</i>	58.0 (44.0-67.0)		0.006	
testicular/gynaecological	59.0 (31.0-62.0)			
vascular-venous lower limbs LL)	64.5 (57.0-75.0)			
thyroids/neck	46.0 (33.0-63.0)			
pulmonary	49.0 (38.0-70.0)			
musculoskeletal	58.0 (47.0-68.0)			
soft tissue	52.0 (39.0-63.0)			
cardiac	66			
	Time of implementation (min.)		p¹	
abdominal/abdominopelvic/urological, <i>median (IQR)</i>	13.0 (10.0-18.0)		<0.001	
testicular/gynaecological	13.0 (12.0-15.0)			
vascular-venous lower limbs LL)	11.5 (10.0-12.5)			
thyroids/neck	12.0 (10.0-15.0)			
pulmonary	10.0 (10.0-10.0)			
musculoskeletal	11.0 (10.0-14.0)			
soft tissue	8.0 (6.0-10.0)			
cardiac	20			
	female	male	P²	
Abdominal/abdominopelvic/urological, <i>n (%)</i>	107 (52.7)	96 (47.3)	0.058	
testicular/gynaecological	2 (22.2)	7 (77.8)		
vascular-venous lower limbs LL)	9 (75.0)	3 (25.0)		
thyroids/neck	19 (76.0)	6 (24.0)		
pulmonary	24 (55.8)	19 (44.2)		
musculoskeletal	72 (51.1)	69 (48.9)		
soft tissue	67 (59.3)	46 (46.7)		
cardiac	1 (100)			
	scheduled	immediate	CPC	P²

Abdominal/abdominopelvic/urological, <i>n</i> (%)	167 (82.3)	34 (16.77)	2 (1.0)	<0.001
testicular/gynaecological	6 (66.7)	2 (22.2)	1 (11.1)	
vascular-venous lower limbs LL)	5 (41.7)	7 (58.3)	0 (0.0)	
thyroids/neck	22 (88.0)	3 (12.0)	0 (0.0)	
pulmonary	14 (33.3)	26 (61.9)	2 (4.8)	
musculoskeletal	98 (69.5)	43 (30.5)	0 (0.0)	
soft tissue	87 (77.0)	26 (23.0)	0 (0.0)	
cardiac	1 (100)	0 (0.0)	0 (0.0)	
	new tests or referrals			
	yes	no		P ²
Abdominal/abdominopelvic/urological, <i>n</i> (%)	86 (42.4)	117 (57.6)		0.029
testicular/gynaecological	4 (44.4)	5 (55.6)		
vascular-venous lower limbs LL)	2 (16.7)	10 (83.3)		
thyroids/neck	13 (52.0)	12 (48.0)		
pulmonary	27 (62.8)	16 (37.2)		
musculoskeletal	74 (52.5)	67 (47.5)		
soft tissue	66 (58.4)	47 (41.6)		
cardiac	1 (100)	0		
	Ultrasound alteration by the doctor			
	yes	no		P ²
Abdominal/abdominopelvic/urological, <i>n</i> (%)	102 (50.2)	101 (49.8)		<0.001
testicular/gynaecological	7 (77.8)	2 (22.2)		
vascular-venous lower limbs LL)	4 (33.3)	8 (66.7)		
thyroids/neck	16 (64.0)	9 (36.0)		
pulmonary	19 (44.2)	24 (55.8)		
musculoskeletal	106 (75.2)	35 (24.8)		
soft tissue	101 (89.4)	12 (10.6)		
cardiac	1 (100)			

¹Kruskal Wallis; ²Chi-square or Fisher's exact test

Table 2: Association between the ultrasound type/group with the general variables and actions after the test.

Ultrasound alterations were found in 65.1% of those conducted, CI: 95% 61.9-68.9%. The most frequent definitive diagnoses (after the five months of monitoring the clinical evolution) were the osteoarticular scans (27.3%), those of soft tissue (21.2%) and urological scans (14.9%). In greater detail: renal/urological pathology (54, 14.92% of the total), musculoskeletal pathology of knee and leg (50, 13.81%), rotator cuff and bicep pathology (49, 13.54%), cysts, nodules and ganglions (30, 8.29%), adenopathy (24, 6.63%), lipoma/lipomatosis (23, 6.35%), biliary pathology (21, 5.80%), pleuropulmonary pathology (20, 5.52%), hepatic pathology (16, 4.42%), thyroid and neck pathology (16, 4.42%), others of soft tissue (13, 3.59%).

Table 3 presents the variables associated with finding an alteration in the ultrasound, considering those in which there was coincidence between the initial ultrasound diagnostic impression of the doctor and the definitive ultrasound diagnosis; through a multivariate analysis and logistical regression. An association was found between ultrasound findings and the type of ultrasound (with the OR being greater in the ultrasound of soft tissue), conducting new tests, masculine sex, age (greater OR if ≥ 80), and lesser with the duration of the examination.

Variables	OR (CI 95%)	p value
Ultrasound type		
Abdominal/abdominopelvic/urological	Ref.	-
Testicular/gynaecological	4.1 (0.8-20.8)	0.085
Thyroids/neck	3.1 (1.2-7.9)	0.022
Musculoskeletal	3.6 (2.1-6.1)	<0.001
Soft tissue	19.9 (9.2-43.0)	<0.001
New tests after ultrasound	3.8 (2.4-5.9)	<0.001
Sex		
Female	Ref.	
Male	1.8 (1.2-2.8)	0.008
Categorised Age (years)		
<40	Ref.	
40-64	2.3 (1.3-4.1)	0.003
65-79	3.0 (1.5-6.0)	0.002
≥80	8.9 (3.2-24.1)	<0.001
Time (min)	1.1 (1-1.1)	0.042
AUC (CI 95%)	0.81 (IC95% 0.77 – 0.85)	
Ref: Reference group; OR: Odds Ratio; CI: Confidence Index; AUC: Area under ROC curve.		

Table 3: Variables associated with ultrasound alteration in patients with ultrasound diagnostic coincidence; logistical regression.

There was coincidence among the initial ultrasound diagnostic impression and after the clinical monitoring in 94.3% (CI: 95% 90.7-95%). There was no ultrasound diagnostic coincidence in 31 cases, of serious pathologies in two cases of carcinoma (of pancreas and urothelial), although both were referred to the corresponding specialist despite the absence of ultrasound findings in the initial examination. The main ultrasound types/groups not coinciding were the abdominal/abdominopelvic (13 cases, 41.9% of total non-coincidence), urological (6, 19.3%), and those of soft tissues (4, 13%). We only found a statistically significant association with taking more actions or diagnostic tests where there was no coincidence (8.8% of actions or tests in non-coincidence vs. 91.2% in coinciding cases) with respect to when it was not done (3.1% vs. 96.9%); $p=0.005$. And with referral to another specialist (87.6 vs. 12.4 according to whether or not there was coincidence), compared to not referring (96.0 vs. 4.0%); $p<0.001$.

Discussion

The results of the study offer important information mainly regarding the feasibility and utility of the POCUS carried out in PC practices. As for the feasibility, we considered the short time of realization, compatibility with the habitual visits and diversity of clinical scenarios where it was applied. Utility took into account the high percentage of initial diagnoses and diagnostic coincidence with the definitive diagnoses considering the next clinical course, and safety with the low percentage of false negatives and none

of them with high clinical repercussion. On the other hand, its development clearly showed the difficulties in carrying out the study, even in providing continuity in healthcare practice in the performance of ultrasounds; which is another indication of its applicability.

The range of modalities of ultrasound scans performed has been very broad, with the abdomino-pelvic and urological, musculoskeletal and soft tissue scans being predominant; all together, these modalities have supposed 83.6% of the total. Only one cardiac scan was performed and no other more specific (mammary, supra-aortic trunks, etc.). This diversity of examinations coincides with what was found in other studies [13], although due to the scarce number of doctors participating in the pilot study, their probable lack of familiarity or skill in certain areas, and being circumscribed to a specific health system, results in discordant revisions that indicate frequent performance of other ultrasounds that in this study were not considered: obstetric, cardiac (only one case), breast, ophthalmological, vaginal or rectal echo-endoscopy, or in emergencies [1,13-16]. This backs the potential for a greater extension of the POCUS, as well as the types performed in this study, to other modalities and clinical scenarios.

The majority of the ultrasounds were done in a scheduled manner, although 27% were immediate in the healthcare visit, a proportion hardly examined in other studies of the area of the PC, although the high volume of examinations performed in the time and their proportion with respect to all the visits, as well as the short

time that the POCUS takes (in our study even the abdominopelvic have a median of 13 minutes), leads to presupposing that a large part of them are feasible of being integrated in the spontaneous visit or on demand [15]. This is important because it backs the use of the ultrasound as another support tool in the usual visit. In other studies the duration of the examinations has been even shorter, even of five minutes [15]. Those of a shorter duration (soft tissues, musculoskeletal, pulmonary) and those that do not require previous preparation (for example, those not requiring fasting) are shown to be most suitable for these examinations integrated in an unscheduled consultation. In short, as some studies show, the POCUS becomes a habitual tool in the practices, with a use that can reach 8% of all of them [15].

As already commented, the examination time has been brief. Those that took longer have been the abdominal/abdominopelvic/urological scans and the testicular/gynaecological scans; even so, both with a median of 13 minutes. Although the time of some studies has been less, one must consider that several of them refer to emergency or screening situations, with a specific and concise focus [2].

The high percentage of findings (65%) found in them endorse the utility of the POCUS, coinciding with other studies [15]. An association of findings has been found with the ultrasound modality, sex and age; as well as the high coincidence (94%) between the initial diagnostic ultrasound and the definitive one based on the later clinical monitoring. On the other hand, other studies show a high diagnostic correlation between the family doctor and the hospital specialist (93% of concordance) and with the radiologists (80-89%) [17].

It is shown to be a safe technique if we consider the fact of not finding diagnostic errors with clinical repercussions. There were only two cases of ultrasounds in which no findings were made and later serious diseases were diagnosed, specifically one of pancreas carcinoma and another of urothelial carcinoma. In both cases, despite not having any findings, other urgent diagnostic tests were requested (an abdominal CT scan that show the pancreas carcinoma) or the patient was sent to other specialists (referral to urology due for hematuria). In addition, significant association was found between taking more actions with there being no diagnostic coincidence in the diagnostic ultrasound. This also shows the integration of the POCUS in the corresponding clinical scenarios and their diagnostic reasoning and handling of uncertainty by the professionals faced with them, with a low proportion of false negatives as described in other studies, which is 5% [18]. In the study by Andersen et al. [15], the POCUS entailed a diagnostic change and the handling plan of half of the patients, in addition to reducing the referrals to the second and third care level also in this proportion; and in this same study aspects of uncertainty and diagnosis were assessed in the sense that the positive findings were classified with certainty (45.7%) and negative with certainty (32.3%), while the uncertain positives or negatives made up 19.5% [15]. The authors comment that the more specific the anatomical area to examine, and the more directed the ultrasound, the greater are the quality and certainty obtained [2].

Despite the musculoskeletal ultrasound and that of soft tissues being much performed modalities, diagnostic-therapeutic manoeuvres (drainage/infiltrations) were done on only 15 cases of the total of the 547 scans, much lower than that referred to in other studies where an ultrasound-guided procedure was done on a third of them [13], perhaps due to a need to acquire more skill in these practices.

The pilot study (qualitative research by survey and narration) examined other aspects related to the difficulties in carrying out the research study, results presented in unpublished congresses, where finally of the nine professionals, three did not carry out or did not provide their ultrasounds. Two referring to practice overload (unanimous reason, 9 out of 9, as the main barrier for the carrying out the study with all its potential and intensity) and lack of support by the organization (7 of 9), and another for instability of a place to work in centers without ultrasound. Another two professionals gathered or recorded a limited number of examinations, much less than those performed. Although this affected the strength of the study, it does reflect, as the pilot study that it is, the reality and obstacles for implanting and making routine a technique that on the other hand is shown to be feasible and useful in PC. And although with a limited number of the total ultrasounds, professionals and geographic location, it is probable that it reflects the reality of the application in other health systems.

It has delimited areas for improvement for the implementation of ultrasound in our organization, providing checklist-type records, focusing the consequent training activities, and indicating institutional aspects that must favor it. On the methodological base and results obtained, it shows that a broader study is pertinent, which also explores the satisfaction of professionals and patients, and compares the more prevalent or relevant scenarios with family doctors who do not perform ultrasound scans. It would also be interesting to carry out and compare the obtained results with other broader studies and in our area with other health systems.

Conclusions

The POCUS is shown to be feasible/compatible with the PC practice (considering duration and modalities), useful (for findings/diagnostic coincidence), safe (providing confidence in the diagnostic-handling and with low false negatives with clinical repercussions). The different care realities could limit the generalization of results, although it also reflects the versatility of the use of the POCUS; with the need to explore/broaden its potential applicability. The organizational aspects and overload of the PC practice can limit its extension.

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Ethical Aspects

The patients received a Patient Information Sheet (PIS) and signed the Informed Consent (IC). The forms were duly coded to keep patient records and data analysis anonymous. The study had the approval of the Research Ethics Committee of Euskadi (CEIm-E), code PS2021046, August 3rd of 2021.

Conflict of Interest

None of the authors presents any conflict of interest. The research group belongs to the Osatzen Group (Basque Family and Community Medicine Society) on ultrasound. Two of the professionals, MAE and MGA, are part of the working group of the Sub-Directorate of PC in the strategy of implementing ultrasound in PC practice. None of the researchers are related to ultrasound companies or products, or receive remuneration for carrying out the study.

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