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Intrauterine Pregnancy Detection and Gestational Age Assessment During Early Pregnancy by a Handheld Point-Of-Care Ultrasound Device Compared to a High-End Ultrasound System. An Accuracy and Reliability Study

Mariela Skendi, Roxane Liard, Charlotte Besacier, Jean-Michel Correas, Sohela Moussaoui, Julie Chastang, Gladys Ibanez

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1 **Title page**

2 **Title:**

3 Intrauterine pregnancy detection and gestational age assessment during early pregnancy
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5 system. An accuracy and reliability study.

6

7 **Authors:**

8 **Skendi Mariela, MD, MSc, marielaskendi@sorbonne-universite.fr** (corresponding
9 author) 1,2

10 **Liard Roxane, MD, MSc roxane.liard@sorbonne-universite.fr** 1

11 **Besacier Charlotte, MD, besacier.charlotte@gmail.com** 1

12 **Correas Jean-Michel, MD, PhD, jean-michel.correas@nck.aphp.fr** 2

13 **Moussaoui Sohela, MD, MSc, sohela.moussaoui@sorbonne-universite.fr** 1

14 **Chastang Julie, MD, MSc, julie.chastang@sorbonne-universite.fr** 1

15 **Ibanez Gladys, MD, PhD, gladys.ibanez@sorbonne-universite.fr** 1,3

16 1. Department of General Practice, Faculty of Medicine, Sorbonne University, Paris,
17 France

18 2. Department of Adult Radiology, Necker Hospital, Paris, France

19 3. INSERM, Institut Pierre Louis d'Epidémiologie et de Santé Publique (IPLESP) Paris,

20 France

21

22 **Word count:** 2333

23 **Keywords:** Accuracy, Reliability, Pregnancy, Gestational age, Ultrasound, Point-of-

24 care ultrasound

25

26 **Abstract**

27 **Objective**

28 The main objective of this study is the evaluation of the accuracy and reliability of a
29 handheld point-of-care ultrasound device (POCUS-hd) for intrauterine pregnancy (IUP)
30 detection compared to comprehensive reference transabdominal ultrasound (TU). The
31 secondary objectives were to evaluate POCUS-hd for intrauterine pregnancy (IUP)
32 detection compared to transabdominal and transvaginal ultrasound (TUTV), evaluate
33 the inter-device agreement and inter-rater reliability of gestational age during early
34 pregnancy.

35 **Methods**

36 It is an observational transverse study with consecutive patient recruitment. Two
37 blinded operators systematically used POCUS-hd and reference transabdominal
38 ultrasound for IUP diagnosis.

39 The accuracy of POCUS-hd for IUP diagnosis was expressed as sensitivity (Se),
40 specificity (Spe), negative predictive value (NPV) and positive predictive value (PPV).

41 The gestational age (GA) was assessed based on the crown-rump length. The reliability
42 and agreement of gestational age evaluation were assessed by Bland-Altman plots,
43 kappa statistic, and intraclass correlation coefficients^o(ICC).

44 **Results**

45 POCUS-hd compared to TU had Se of 95-100%, Spe of 90-100%, PPV of 95-100%
46 and NPV of 90-100%. Inter-rater agreement for IUP detection using POCUS-hd was

47 very good, kappa=1.0; CI95% [0.9-1.0]. The inter-device agreement limits (mean
48 difference \pm 2SD) for GA were: -3 to +2.3 days by Operator 1, -3.4 to +3.3 days by
49 Operator 2 for POCUS-hd vs. TU and -3.1 to +2.3 days for POCUS-hd versus TUTV.

50 **Conclusion**

51 This handheld POCUS device is an accurate and reliable diagnostic tool that can be
52 used for IUP positive findings and GA assessment during early pregnancy by clinicians
53 in family planning settings or general practice.

54

55

56

57

58 **Background**

59 The past decade saw the development and increased popularity of new point-of-care
60 ultrasound (POCUS) devices. These portable devices have very fast start times, when
61 compared to conventional ultrasound machines, and enable clinicians to perform
62 POCUS at the bedside in clinical units. The further miniaturization of the machines
63 gave birth to a new concept - “echoscopy” – defined in 2013 by the European
64 Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB) [1, 2] as
65 part of three levels of ultrasound: echoscopy, POCUS and comprehensive ultrasound.
66 While POCUS highlights the setting where the ultrasound exam is performed,
67 echoscopy is defined by its ability to answer a simple targeted clinical question asked
68 by the clinician at the bedside that can be documented in the patient’s chart and does not
69 require a detailed imaging report. It is the intention of the clinician and the need to
70 answer a specific clinical question that defines the type of ultrasound performed. Should
71 the physician wish to perform a detailed exam to explore a region of organs,
72 sophisticated devices used for comprehensive ultrasound machines are better adapted.
73 Echoscopia and POCUS can be performed with handheld devices while comprehensive
74 ultrasound with more sophisticated equipment (2).

75 For patients presenting lower abdominal pain and/or vaginal hemorrhage in early
76 pregnancy, it is important for the clinician both to confirm the presence of an
77 intrauterine pregnancy (IUP) as well as estimate the gestational age (GA), for clinical
78 decision making later in pregnancy or voluntary pregnancy termination [3]. Before
79 using these new miniaturized ultrasound devices to answer such clinical questions in

80 everyday practice, it is important to evaluate their accuracy and reliability compared to
81 a high-end system.

82 The principal objective was the evaluation of the accuracy and reliability of handheld
83 point-of-care ultrasound device (POCUS-hd) for IUP detection compared to
84 comprehensive reference transabdominal ultrasound (TU). The secondary objectives
85 were to evaluate POCUS-hd for IUP detection compared to transabdominal and
86 transvaginal ultrasound (TUTV), evaluate the inter-device agreement and inter-rater
87 reliability in calculating GA in the first trimester of pregnancy.

88

89 **Methods**

90 **Study Design**

91 This was an observational transverse monocentric study conducted according to the
92 STARD and GRRAS guidelines for accuracy and reliability [4, 5]. All studies were
93 performed at the Family Planning Clinic at the Cochin Port-Royal University Hospital
94 in Paris, France.

95 The first part of the study compared the accuracy of a POCUS-hd compared to TU and
96 TUTV for the detection of IUP and the inter-operator agreement for IUP detection.

97 The second part of the study evaluated the inter-device agreement on GA measurement.
98 The GA obtained using POCUS-hd was compared to the TU measurement. The inter-
99 rater variability for GA measurement was then calculated for each operator. Two
100 blinded operators scanned independently the same population of patients in alternating
101 order, on the same day at 5-10 minutes intervals. Operator 1 performed POCUS
102 followed by TU for all patients and a TUTV for all pregnancies younger than 6 weeks
103 of gestation or whenever the embryo could not be visualized transabdominally
104 according to the usual practice at the clinic. Both POCUS and the reference
105 comprehensive ultrasound were performed on the same day during the patient's visit to
106 the family planning clinic.

107

108 Operator 2 performed POCUS-hd followed only by a TU. At the end of each study,
109 both operators would fill a written report and would communicate the results of their

110 respective scan to the patient. Patients had no specific preparation for the study, like
111 fasting or full bladder requirement.

112 **IUP definition and GA calculation**

113 The presence of an IUP was confirmed by the visualization of the double decidual sac
114 sign on B-mode with either an embryo or a yolk sac.

115 The GA was assessed based on the crown-rump length (CRL) using the following
116 equation [11]: $gestational\ age\ (days) = 8.052 * (1.037 * CRL)^{1/2} + 23.73$.

117 The mean diameter of the gestational sac was not used for GA calculation due to its
118 higher variability and less precise GA estimation [6-12]. Basic settings were used such
119 as gain, depth, zoom, and use of calipers for measurements of CRL.

120

121 **Population**

122 We aimed to recruit 65 consecutive patients who visited the Family Planning Clinic at
123 the Cochin Port-Royal University Hospital between May and July 2016. Among this
124 population, pregnancy was either confirmed or suspected. Patients would come in with
125 a positive urinary pregnancy test, a positive plasmatic beta human chorionic
126 gonadotropin (hCG), a delay in the onset of menses, abdominal pain with/or vaginal
127 bleeding and for a follow-up visit to confirm pregnancy termination. Patients were
128 included if they were at least 18 years of age. Patients were excluded from the study if
129 they were under 18 years, had twin gestations, refused to sign a consent form or if the

130 image acquisition was incomplete due to technical difficulties with the ultrasound
131 machine.

132 **Operators**

133 Operator 1, was a general practitioner (GP) who had been working and using ultrasound
134 at the family planning clinic for 5 years. Operator 2, was a GP who had a general 2-year
135 ultrasound diploma and had finished a 6-month training at the family planning clinic.

136

137 **Ultrasound Device**

138 POCUS was performed with a handheld Visiq Philips device that weighed 1 kg, had an
139 average start time of 30 seconds and was connected to a C5-2°MHz transducer through
140 USB port. The comprehensive reference ultrasound was performed on the ProSound
141 Alpha 6 machine using UST-9123 6-2 MHz and UST-9124 7.5-3 MHz transducers.

142

143 **Data Storage and Interpretation**

144 Images obtained by POCUS-hd were stored as DICOM files on the Visiq Philips
145 ultrasound device. Images obtained by the transabdominal ultrasound machine were
146 stored on the ProSound Alpha 6 machine. Both operators recorded their findings and
147 image interpretations on paper files.

148 **Figure 1**

149 **Statistical Analysis**

150 The accuracy of POCUS-hd was calculated in terms of sensitivity, specificity, negative
151 predictive value and positive predictive value using contingency tables for Operators 1
152 and 2. Inter-rater agreement on IUP detection was evaluated by the kappa statistic.
153 Inter-device agreement for GA evaluation was calculated using Bland-Altman plots.
154 Inter-rater variability for GA measurement with POCUS-hd was calculated using the
155 intraclass correlation coefficient (ICC) and Bland-Altman plots [12]. Data analysis was
156 performed by the Department of General Practice at Sorbonne University, using Stata
157 and R Studio software.

158 **Results**

159 Among the 65 eligible women, 57 were enrolled in the study (Table 1). On standard
160 transabdominal ultrasound, there were 37 IUPs detected, among whom 34 had visible
161 embryos, 3 had gestational sacs with yolk sacs according to POCUS-hd. On TUTV
162 there were 45 IUP detected, among whom 41 had visible embryos, 4 had gestational
163 sacs with yolk sacs according to TUTV.

164

165 **Figure 2.** Flow diagram, POCUS-hd versus reference standard transabdominal
166 ultrasound.

167 **Supplemental material 1**

168 *Accuracy*

169 POCUS-hd accuracy was calculated through contingency tables. The sensitivity of
170 POCUS-hd for IUP detection was 95-100% (35/37 for Operator 1 and 37/37 for
171 Operator 2) when compared to TU alone. The specificity for POCUS-hd for IUP
172 detection was 90-100% (18/20 for Operator 1 and 20/20 for Operator 2) when compared
173 to TU alone. The PPV was 95-100% (35/37 Operator 1, 37/37 Operator 2). The NPV
174 was 90-100% (18/20 Operator 1, 20/20 Operator 2).

175 The sensitivity of POCUS-hd for IUP detection was 82% (37/45 by Operator 1) when
176 compared to TUTV. The specificity for POCUS-hd for IUP detection was 100% (20/20
177 by Operator 1) when compared to TUTV. The PPV was 100% (37/37) and NPV was
178 60% (12/20) where the reference ultrasound was TUTV.

179 Inter-rater agreement for IUP detection by POCUS-hd was excellent, kappa=1.0; CI_{95%}
180 [0.9-1.0].

181

182 **Table 2:** Diagnostic accuracy of echoscopy for intrauterine pregnancy detection
183 compared to comprehensive ultrasound (n=57)

184

185 *Reliability*

186 Agreement limits of POCUS-hd vs. TU (mean difference \pm 2SD) were -3.0 to +2.3 days
187 for Operator 1 and -3.4 to +3.3 days for Operator 2. Agreement limits of POCUS-hd vs.
188 TUTV were -3.1 to +2.3 days. The inter-device agreement (POCUS-hd vs. TU and
189 POCUS-hd vs. TUTV) for GA estimation was very good.

190 **Figure 3:** Inter-device variability

191 The inter-rater agreement of GA by POCUS-hd was excellent, ICC = 0.99, CI 95%
192 [0.98 - 0.99] and agreement limits on the Bland-Altman plot were -2.7 to +3 days.

193 **Figure 4:** Inter-rater variability

194

195

196 **DISCUSSION**

197 The handheld POCUS device, compared to transabdominal ultrasound and
198 transabdominal ultrasound completed with transvaginal, was highly accurate for IUP
199 detection and GA assessment. The study showed excellent agreement of POCUS-hd
200 versus TU and POCUS-hd versus TUTV for GA measurement as agreement limits of
201 POCUS-hd [± 3 days] are within the precision limits of ultrasound dating of [± 5
202 days] days used in clinical practice [6, 13]. The reproducibility of gestational age
203 measurements by POCUS-hd between the 2 operators was very good.

204 POCUS-hd is intended to be used by clinicians who need to determine the location of a
205 pregnancy in the first trimester at the bedside during the clinical examination. They may
206 then, depending on their abilities, date the pregnancy if needed [7]. In the event of a
207 negative result where intrauterine pregnancy cannot be confirmed, it is up to the
208 clinician to decide whether to continue the investigations and within what time frame to
209 repeat POCUS, or request a comprehensive ultrasound. Of the 65 patients recruited for

210 this study, 8 were excluded because they were under 18 years of age. The remaining 57
211 patients, all consented to be part of the study.

212 To this day, only a few studies have evaluated the accuracy of a handheld ultrasound
213 device for routine obstetrical examination during early pregnancy but there is no study
214 that evaluates their accuracy and reliability in a context of pregnancy termination. A
215 systematic review published in 2019 by Rykkje et al. comparing hand-held ultrasound
216 devices with high-end ultrasound showed a good overall agreement for obstetrics and
217 gynecology use. The results of our study with a Visiq Philips handheld device are
218 comparable to the results of 3 obstetrics/gynecology studies during the first semester at
219 an emergency setting in terms of reliability where a Vscan was used [14]. One of the
220 strengths of this study is to evaluate another handheld device, Visiq/Philips, in a context
221 of pregnancy termination in a family planning clinic.

222

223 Sayasneh et al. evaluated the validity of a POCUS-hd device, Vscan, in a population of
224 101 patients with signs of pelvic pain or hemorrhage during their first trimester. There
225 was “good” to “very good” concordance between the Vscan and the transabdominal and
226 transvaginal ultrasound for the detection of an embryo, a gestational sac, cardiac
227 activity, with kappa coefficients of 0.844, 0.843 and 0.729, respectively ($p < 0.0001$).
228 The concordance for CRL and mean diameter of the gestational sac measurement was
229 very good with an ICC > 0.9 ($p < 0.0001$) [15]. These results are in agreement with the
230 results of our study covering 37 women which found a good concordance between
231 POCUS-hd and the transabdominal ultrasound to measure gestational age based on
232 crown-rump length, ICC = 1.0 ($p < 0.0001$).

233 Several studies on the different fields of application of POCUS suggest that its greatest
234 potential and impact on morbidity and mortality is in obstetrics. A study on the use of
235 POCUS by midwives in Zambia, for example, showed that they can be trained to
236 perform POCUS, answer simple obstetric clinical questions, and impact clinical
237 decision-making [16-19].

238 One of the limitations of this study is that it does not assess intra-operator variability.
239 This possibility was discussed during the design of the study but additional measures
240 would have extended the duration of the examination and might have become
241 uncomfortable for patients. For this reason and for patients' comfort, transvaginal
242 ultrasound was not repeated by Operator 2 but was rather performed only once by
243 Operator 1 as part of the usual practice.

244 Among obstetric studies, bedside ultrasound is easily accepted and allows accurate
245 monitoring of pregnancy after 5 weeks of gestation. Pelvic pain in early pregnancy may
246 be secondary to an ectopic pregnancy in the absence of a uterine gestational sac and the
247 presence of an adnexal mass or intraperitoneal free fluid. The results of a meta-analysis
248 on the diagnosis of ectopic pregnancy by bedside ultrasound performed by emergency
249 physicians show a high specificity and high sensitivity in the localization of a pregnancy
250 but remain operator-dependent [17, 20-23].

251 The results of our study showed that the diagnostic performance of POCUS-hd to detect
252 intrauterine pregnancy was satisfactory and could be used in the family planning clinic.
253 The reliability of a handheld POCUS-hd device to evaluate GA during the first trimester
254 was comparable to conventional ultrasound with an accuracy of +/- 3 days. The

255 population in this study included adult women in the first trimester of their pregnancy.
256 However, the study may be extended to other populations. POCUS-hd can also be used
257 in other clinical situations such as confirming the proper positioning of an intrauterine
258 device. In the context of gynecological emergencies, it can assess the viability of the
259 pregnancy. POCUS-hd can also be used to diagnose other (non-obstetric) pathologies
260 such as a pelvic mass or intraperitoneal free fluid. Its usefulness in cardiac, renal,
261 vascular, hepatosplenic and musculoskeletal pathologies has been well-established.

262 As technology progresses, both image resolution and POCUS-hd affordability will
263 undoubtedly improve. In the near future, physicians and medical students will be
264 equipped more easily and educators will teach ultrasound skills during medical school
265 or during continuing medical education activities.

266

267 **CONCLUSIONS**

268 This handheld POCUS device seems to be an accurate and reliable diagnostic tool that
269 can be used for IUP detection and GA assessment during early pregnancy by clinicians
270 in the family planning setting or general practice. These portable devices enable
271 clinicians to perform POCUS at the bedside in clinical units, help improve the accuracy
272 of the physical exam and improve patient care.

273

274

275 **Ethics statement and consent**

276 Patients were informed before the study orally and in writing. All patients signed a
277 written consent form before participating in the study. In conformity with the French
278 regulation, authorizations for the study were obtained by the institution of Advisory
279 Committee on the Processing of Research Information (CCTIRS) and National Data
280 Protection Commission (CNIL) #2070527. Considering the study did not change the
281 usual practice and it did not involve any risk for the patients, a formal ethical approval
282 was not required. Patients or the public were not involved in the design, or conduct, or
283 reporting, or dissemination plans of this research.

284

285 **DECLARATIONS**

286 **List of Abbreviations**

287 Pocus: point-of-care ultrasound; POCUS: echoscopy device; IUP: intrauterine
288 pregnancy; TU: transabdominal ultrasound; TUTV: transabdominal ultrasound
289 completed by a transvaginal approach; ICC: intraclass correlation coefficient; GA:
290 gestational age; CRL: crown-rump length; HCG: human chorionic gonadotropin.

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293 study duration, at the request of the author (MS). Philips had no role in study design,
294 data collection, analysis, decision to publish, or preparation of the manuscript.

295 **Authors' contributions**

296 MS, CB, JMC and GI designed the study. All authors read and approved the final
297 manuscript.

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300

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370 gestational age in pregnant females. Am J Emerg Med. 2012;30:1627–9.

371

372

373

374 **Table 1:** Patient characteristics (n=57)

375

Patients	m ± sd
Age (years)	27.3 ± 6
Gestational age (days)	50.9 ± 14
Weight (kg)	63.6 ± 13
Height (cm)	165.7 ± 6
Body Mass Index (kg/m ²)	23.2 ± 5

376

Handheld ultrasound device in early pregnancy

Table 2: Diagnostic accuracy of echoscopy for intrauterine pregnancy detection compared to comprehensive ultrasound (n=57)

		Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value
Transabdominal Ultrasound (TU)	Operator 1	95%	100%	95%	90%
	Operator 2	100%	100%	100%	100%
<hr/>					
Transabdominal and Transvaginal Ultrasound (TUTV)	Operator 1	82.3%	100%	100%	60%

Handheld ultrasound device in early pregnancy

Figure Captions

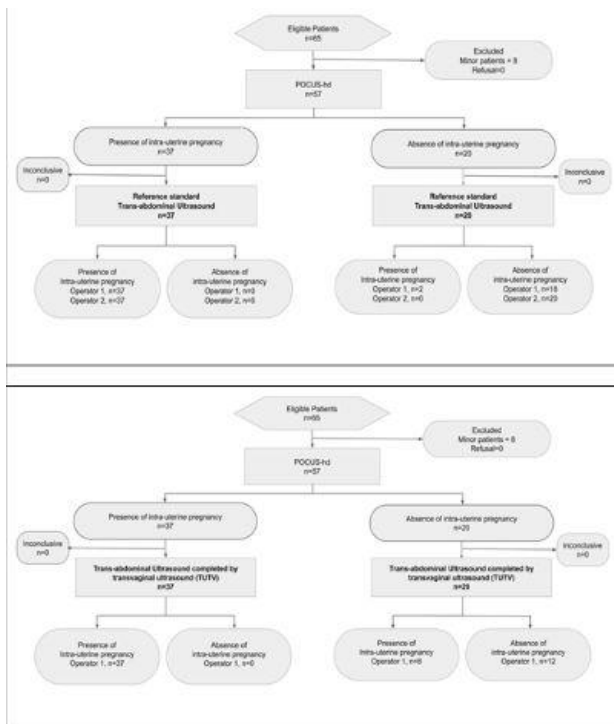
Figure 1

POCUS handheld device (on the left) and comprehensive ultrasound device (on the right) used for IUP detection and gestational age measurement.



Figure 2

Flow diagram of POCUS-hd accuracy where the reference is transabdominal ultrasound performed by Operator 1 and Operator 2



Handheld ultrasound device in early pregnancy

Handheld ultrasound device in early pregnancy

Figure 3

Plot of gestational age measured by POCUS-hd versus transabdominal reference ultrasound (TU), by Operator 1 (top left), Operator 2 (middle right).

Plot of gestational age measured by POCUS-hd versus transabdominal ultrasound completed by transvaginal ultrasound (TUTV), by Operator 1 (bottom left).

Bland-Altman plot comparing gestational age measurement by point-of-care ultrasound handheld device (POCUS-hd) versus Transabdominal ultrasound (TU) by Operator 1 (top right), Operator 2 (middle right).

Bland-Altman plot comparing gestational age measurement by point-of-care ultrasound handheld device (POCUS-hd) versus Transabdominal ultrasound completed by transvaginal approach (TUTV) by Operator 1 (bottom right).

Figure 4 Inter-rater variability for gestational age measurement by POCUS-hd

