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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**

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1 **Title page**

2 **Title:**

3 Intrauterine pregnancy detection and gestational age assessment during early pregnancy  
4 by a handheld point-of-care ultrasound device compared to a high-end ultrasound  
5 system. An accuracy and reliability study.

6

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21

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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<sup>o</sup>(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

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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<sub>95%</sub>  
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 [ $\pm 3$  days] are within the precision limits of ultrasound dating of [ $\pm 5$   
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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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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**References**

- 304 1. Moore CL, Copel JA. Point-of-Care Ultrasonography. *New England Journal of*  
305 *Medicine*. 2011;364:749-57.
- 306 2. Birth of Echoscropy- The EFSUMB Point of View. *Ultraschall in der Medizin -*  
307 *European Journal of Ultrasound*. 2013;34:92-92.
- 308 3. Diagnostic Ultrasonography in Women's Health Care (Position Paper) [Internet].  
309 <http://www.aafp.org/about/policies/all/ultrasonography-diagnostic.html> [cited 2016 Jul  
310 26]
- 311 4. Bossuyt PM, Reitsma JB, Bruns DE, Gatsonis CA, Glasziou PP, Irwig LM, et al.  
312 Towards complete and accurate reporting of studies of diagnostic accuracy: the STARD  
313 initiative. *Fam Pract*. 2004;21:4-10.
- 314 5. Kottner J, Audigé L, Brorson S, Donner A, Gajewski BJ, Hróbjartsson A, et al.  
315 Guidelines for Reporting Reliability and Agreement Studies (GRRAS) were proposed. *J*  
316 *Clin Epidemiol*. 2011;64:96-106.1.
- 317 6. Salomon LJ, Alfirevic Z, Bilardo CM, Chalouhi GE, Ghi T, Kagan KO, et al. ISUOG  
318 practice guidelines: performance of first-trimester fetal ultrasound scan. *Ultrasound*  
319 *Obstet Gynecol*. 2013;41:102-13.
- 320 7. Lavoué V, et al. French guidelines for diagnostic criteria for nonviable pregnancy  
321 early in the first trimester and for management of threatened miscarriage and nonviable  
322 pregnancy (except uterine evacuation). *J Gynecol Obstet Biol Reprod (Paris)* 2014.

- 323 8. Delabaere A, et al. Definition of pregnancy losses: Standardization of terminology  
324 from the French National college of Obstetricians and Gynecologists (CNGOF). J  
325 Gynecol Obstet Biol Reprod (Paris) 2014, Dec; 43(10):756-63.
- 326 9. Kaur A. Transvaginal ultrasonography in first trimester of pregnancy and its  
327 comparison with transabdominal ultrasonography. J Pharm Bioallied Sci. 2011;3:329-  
328 38.
- 329 10. Robinson HP, Sweet EM, Adam AH. The accuracy of radiological estimates of  
330 gestational age using early fetal crown-rump length measurements by ultrasound as a  
331 basis for comparison. Br J Obstet Gynaecol. 1979;86:525-528.
- 332 11. Salomon LJ. [How to date pregnancy?]. J Gynecol Obstet Biol Reprod (Paris).  
333 2011;40:726-33.
- 334 12. Bland JM, Altman DG. Statistical methods for assessing agreement between two  
335 methods of clinical measurement. Lancet. 1986;1:307-10.
- 336 13. Butt K, Lim K, Society of Obstetricians and Gynaecologists of Canada.  
337 Determination of gestational age by ultrasound. J Obstet Gynaecol Can. 2014;36:171-  
338 83.
- 339 14. Rykkje, A.; Carlsen, J.F.; Nielsen, M.B. Hand-Held Ultrasound Devices Compared  
340 with High-End Ultrasound Systems: A Systematic Review. Diagnostics 2019, 9, 61.
- 341 15. Sayasneh A, Preisler J, Smith A, Saso S, Naji O, Abdallah Y, et al. Do pocket-sized  
342 ultrasound machines have the potential to be used as a tool to triage patients in  
343 obstetrics and gynecology? Ultrasound Obstet Gynecol. 2012;40:145-50.

- 344 16. Richardson A, Hopkisson J, Campbell B, Raine-Fenning N. Use of the double  
345 decidual sac sign to confirm intra-uterine pregnancy location prior to ultrasonographic  
346 visualisation of embryonic contents: a diagnostic accuracy study. *Ultrasound Obstet*  
347 *Gynecol.* 2016;49:643-648.
- 348 17. Dietrich CF, Goudie A, Chiorean L, Cui XW, Gilja OH, Dong Y, et al. Point of  
349 Care Ultrasound: A WFUMB Position Paper. *Ultrasound Med Biol.* 2016;43:49-58.
- 350 18. Kimberly HH, Murray A, Mennicke M, Liteplo A, Lew J, Bohan JS, et al. Focused  
351 maternal ultrasound by midwives in rural Zambia. *Ultrasound Med Biol.* 2010;36:1267–  
352 72.
- 353 19. Liu L, Hill K, Oza S, Hogan D, Chu Y, Cousens S, et al. Levels and Causes of  
354 Mortality under Age Five Years. In: Black RE, Laxminarayan R, Temmerman M,  
355 Walker N, editors. *Reproductive, Maternal, Newborn, and Child Health: Disease*  
356 *Control Priorities, Third Edition (Volume 2)* [Internet]. Washington (DC): The  
357 International Bank for Reconstruction and Development / The World Bank; [2016 Sep  
358 28].
- 359 20. Lijmer JG, Mol BW, Heisterkamp S, Bossel GJ, Prins MH, van der Meulen JH, et  
360 al. Empirical evidence of design-related bias in studies of diagnostic tests. *JAMA.*  
361 1999;282:1061–6.
- 362 21. Stein JC, Wang R, Adler N, Boscardin J, Jacoby VL, Won G, et al. Emergency  
363 physician ultrasonography for evaluating patients at risk for ectopic pregnancy: a meta-  
364 analysis. *Ann Emerg Med.* 2010;56:674–83.

365 22. Saul T, Lewiss RE, Rivera MDR. Accuracy of emergency physician performed  
366 bedside ultrasound in determining gestational age in first trimester pregnancy. Crit  
367 Ultrasound J. 2012;4:22.

368 23. Bailey C, Carnell J, Vahidnia F, Shah S, Stone M, Adams M, et al. Accuracy of  
369 emergency physicians using ultrasound measurement of crown-rump length to estimate  
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

<b>Patients</b>	<b>m ± sd</b>
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 <sup>2</sup> )	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)

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

# Handheld ultrasound device in early pregnancy

## Figure Captions

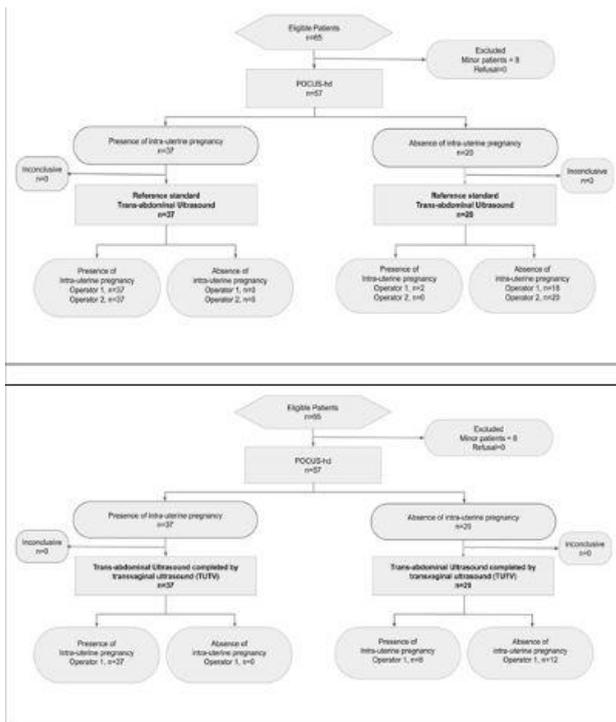
### Figure 1

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

