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Fertility and pregnancy outcomes in patients with bicorporeal uterus and blind hemivagina: 20 years of experience in a tertiary referral gynaecological department

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1 **Fertility and pregnancy outcomes in patients with bicorporeal uterus and blind**
2 **hemivagina: 20 years of experience in a tertiary referral gynaecological**
3 **department.**

4
5 **Short title:** Fertility in patients with bicorporeal uterus

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18 **Abstract**

19

20 **Background:** To evaluate fertility and pregnancy outcomes in patients with uterus
21 bicorporeal and blind hemivagina. Our second objective was to investigate factors
22 predicting fertility and pregnancy outcomes in those patients.

23 **Material and Methods:** We conducted a retrospective analysis in a tertiary referring
24 gynaecological department, in France. We included all patients with uterus bicorporeal
25 and blind hemivagina who underwent at least one surgery in our centre. Initial
26 characteristics of the patients included were extracted from their medical charts and
27 patients were contacted to assess their fertility and pregnancies outcomes upon their
28 consent to participate to the study.

29 **Results:** Between 1989 and 2010, 79 patients fulfilled inclusion criteria and were
30 selected for analysis. Mean follow up of those patients was of 16.15 (QI 10 - 21) years.

31 Forty-six patients (58.2%) returned the survey and among them, 21 (45.7%) were
32 fertile, 8 (17.4%) were infertile and 17 (37%) never attempted to get pregnant following
33 initial management. Forty-nine pregnancies were included to assess pregnancies
34 outcomes: 11 (22.5%) early miscarriages, 1 (2.0%) extra-uterine pregnancy, 2 (4.1%)
35 second semester miscarriages and 35 (71.4%) led to living birth. Nineteen (54.3%)
36 deliveries occurred by caesarean section and 14 (40.0%) by vaginal delivery. Fifteen
37 pregnancies (42.9%) were complicated. In univariate analysis, adhesiolysis performed
38 at the time of initial surgery was the only factor associated with infertility ($p = 0.004$).

39 **Conclusions:** Fertility seems to be perfectly conserved in those patients and they do not
40 have increased rate of adverse pregnancies outcomes.

41

42 **Keywords:** uterine malformation; bicorporeal uterus; blind hemivagina; fertility;
43 pregnancy outcomes

44

45

46 **Introduction**

47
48 The prevalence of congenital uterine malformations in patients could be as high
49 as 7% [1,2]. Bicornuate uterus, resulting from a complete failure of fusion of the two
50 müllerian ducts, account for 11% of uterine malformations. The association of
51 bicornuate uterus, blind hemivagina and ipsilateral renal agenesis constitutes the
52 Herlyn- Werner- Wunderlich syndrome [3].

53 It is generally accepted that uterine malformations could be held responsible for
54 altered fertility, mostly because their prevalence seems higher in patients with infertility
55 than their fertile counterparts [1,2]. However, studies specifically evaluating fertility in
56 patients with bicornuate uterus are rare and available data are conflicting [4–7]. Some
57 authors have reported pregnancy outcomes of patients with bicornuate uterus and
58 blind hemivagina albeit from small cohorts, since this specific entity is quite rare. While
59 they consistently report a higher risk of premature delivery, preeclampsia, or breech
60 presentation [6,8,9], whether it has impact on the early or late miscarriage rate or not
61 remains unclear [6,8]. Furthermore, to the best of our knowledge, factors predicting
62 fertility and pregnancy outcomes have not been reported and this would be highly
63 relevant to help clinicians counsel patients who wish to conceive.

64 The main objective of our study was therefore to evaluate fertility and pregnancy
65 outcomes in patients with bicornuate uterus and blind hemivagina. Our second
66 objective was to investigate factors predicting fertility and pregnancy outcomes in those
67 patients.

68

69

70 **Material and Methods**

71 Study population

72 We conducted a retrospective analysis of patients managed between 1989 and 2010 in
73 our tertiary referral gynaecological department of the Centre Hospitalier
74 Intercommunal de Creteil, France. All patients referred for a bicorporeal uterus and a
75 blind hemivagina were included, which correspond to patients classified U3C2V2
76 according to the latest European Society of Human Reproduction and Embryology
77 (ESHRE) classification of Mullerian anomalies [10]. Patients with other malformations
78 such as septate uterus (U2) and unicervical bicornuate (U3C0) uterus were excluded. All
79 patients included had their diagnosis confirmed by both a clinical examination and an
80 imaging exam.

81 Initial characteristics of the patients included were extracted from their medical charts:
82 demographic data, symptoms leading to the diagnosis, clinical and initial radiological
83 assessment of the malformation. Surgical management was decided on by a surgical
84 committee and was mostly based on vaginal unification for pain relief and exploratory
85 laparoscopy to understand the whole malformation and detect complications. Some
86 patients benefited from a two - steps procedures, to relief symptoms (drainage of
87 hemocolpos for example) first and then to surgically treat their uterine malformation.
88 Decision to perform a hemi - hysterectomy or a unilateral salpingectomy was mostly
89 based on the pre operative imaging work up and, whenever performed, on the
90 laparoscopic evaluation of the uterus and the fallopian tube. Additional procedures
91 depended on the pre-operative workup and per-operative findings. Each patient
92 benefited from a personalized procedure based on his symptoms, his malformation and
93 the pre operative work up. All surgically removed specimens were addressed for

94 pathological analysis. Post-operative follow up included at least one visit 1 month after
95 the operation.

96 To assess fertility and pregnancy outcomes, all the patients were then sent a letter
97 explaining the objectives of the study and offering them the opportunity to participate.
98 Those who agreed were invited to fill in the attached questionnaire. Patients who had
99 not returned the survey within a month were contacted by phone. The questionnaire
100 included questions about their desire to conceive and fertility/pregnancy outcomes.
101 Infertility was defined as either being unable to get pregnant or requiring medical
102 assisted procreation (MAP). Patients not wishing to conceive were excluded from the
103 calculation of the fertility rate. Some patients had multiple pregnancies during the follow
104 up period and each pregnancy was entered individually in our pregnancy outcome
105 analysis. The following pregnancy outcomes were evaluated: early and second trimester
106 miscarriages, pregnancy - induced hypertension or preeclampsia, term of delivery, foetal
107 presentation at delivery, mode of delivery (caesarean section or vaginal delivery), post-
108 partum haemorrhage. Pregnancy - induced hypertension was defined as an elevation of
109 blood pressure over 140 mmHg for systolic and / or 90 mmHg for diastolic in pregnant
110 patients after 20 weeks of gestation. Preeclampsia was defined as the concomitant
111 presence of a pregnancy - induced hypertension and of a proteinuria. An early
112 miscarriage was defined as a miscarriage occurring before 12 weeks of amenorrhea. A
113 premature delivery was defined as a delivery occurring between 26 and 37 weeks of
114 amenorrhea. Post-partum haemorrhage was defined as bleeding at the time of delivery:
115 > 500 ml for a vaginal delivery and > 1 L for patients with a caesarean delivery (which
116 was the definition of the post partum haemorrhage used at the time patients were
117 included).

118 Statistical analyses

119 The database was managed using Excel (Microsoft Corporation, Redmond, WA, USA) and
120 statistical analyses were performed using R software (3.3.1 version, available online).
121 Statistical analysis was based on the Student's t test for continuous variables and the χ^2
122 test or Fisher's exact test for categorical variables. Values of $p < 0.05$ were considered to
123 denote significant differences.

124 Ethical approval

125 This study was approved by the Institutional Review Board of Paris X (04.07.2014).

126

127

128

129 **Results**

130

131 Patients included and initial characteristics

132 Between 1975 and 2010, 87 patients were treated in our centre for blind hemivagina.

133 Among them, 79 had a bicorporeal uterus and were included for further analysis. The

134 mean follow up of the patients was 16.15 (QI 10 – 16) years.

135 Dysmenorrhea (57%) and menometrorrhagia (25%) were the two most frequent

136 symptoms leading to the diagnosis of the uterine malformation (Table 1).

137 Ultrasonography (88.6%) was the most commonly used imaging technique to initially

138 assess the malformation. Twenty patients (25.3%) had an MRI to confirm the diagnosis.

139 Initial surgical procedures and pathological findings are presented in Table 2. Most

140 patients (n=74, 93.7%) had a diagnostic laparoscopy and vaginal unification (n=62,

141 82.3%). Postoperative complications, all severity included, occurred in eight patients

142 (10.1%). None of them occurred following the explorative laparoscopy.

143 Endometriosis was diagnosed in 13 (16.5%) patients in total : on preoperative MRI in

144 three patients (3.8%), perioperatively in seven (8.9%), and on pathological analysis of

145 the surgical specimen in three (3.8%).

146 Fertility and pregnancy outcomes

147 Figure 1 presents the flow chart of the fertility and pregnancy survey. Forty – six

148 patients (58.2%) returned the survey and among them, 17 (36.9%) never attempted to

149 get pregnant following initial management. The fertility rate in patients wishing to

150 conceive was of 72.4%. Five patients had primary infertility and three secondary

151 infertility. The origin of infertility were of the following: tubal (n = 2), uterine (n = 1),

152 cervical with anti-spermatozoid antibodies (n = 1), unknown (n = 4). Forty-nine

153 pregnancies in 28 patients were included to assess pregnancy outcomes: 11 (22.5%)

154 early miscarriages, one (2.0%) extra-uterine pregnancy, two (4.1%) second trimester

155 miscarriages and 35 (71.4%) led to a live birth. Three patients underwent cervical
156 cerclage (MccDonald technic) and two of them had a subsequent second trimester
157 miscarriage.

158 Table 3 presents obstetrical outcomes of the 35 pregnancies resulting in live birth.
159 Nineteen (54.3%) deliveries occurred by caesarean section and 14 (40.0%) by vaginal
160 delivery. Seven pregnancies (20%) were complicated by a premature delivery: four
161 were spontaneous and three induced in response to a medical condition (diabetes and /
162 or preeclampsia). Other complications were registered: four (11.4%) pregnancy -
163 induced hypertension or preeclampsia and three (8.6%) by post-partum haemorrhage.
164 No patient delivered before 32 weeks of amenorrhea and all the patients with a live
165 birth had a healthy infant.

166 In univariate analysis, adhesiolysis performed at the time of initial surgery was the only
167 predicting factor of infertility ($p = 0.004$) (Table 4). Patients whose malformations were
168 discovered following pelvic sepsis were more likely to have post-partum haemorrhage
169 ($p = 0.02$). There was a trend (without reaching statistical significance) for patients who
170 had undergone cervical stomatoplasty to be more at risk of second trimester
171 miscarriage ($p = 0.05$).

172

Discussion

173
174
175 This retrospective study of a large cohort of patients with blind hemivagina and
176 bicorporeal uterus spanning over 20 years of experience, confirms previous reports that
177 neither fertility nor pregnancy outcomes are affected by this malformation. After 16
178 years of follow up, 17.4% were infertile. Twenty-eight patients had 45 pregnancies:
179 around 25% had early miscarriage and 35 pregnancies led to live births. In univariate
180 analysis, adhesiolysis performed at the time of initial surgery was the only predicting
181 factor of infertility.

182 Surgical management of patients with blind hemivagina and bicorporeal uterus
183 could be done in a single surgical procedure. However, our experience of such patients
184 convinced us they might truly benefit from a two steps approach. While first surgery is
185 commonly performed in an emergency context to ease the pain, it enables the surgical
186 team to conduct a complete work up of the malformation to offer the patients the most
187 personalized surgery.

188 We found that fertility was conserved in patients with bicorporeal uterus with
189 only eight patients (17.4%) reporting infertility during the long-term follow up, which is
190 comparable to the rate reported in the general population [11]. This is consistent with a
191 previous study of 49 patients with didelphic uterus with a longitudinal vaginal septum
192 [12]. Similarly, a recent meta-analysis found that bicorporeal uterus was not a risk
193 factor for infertility [8]. The only predictive factor of infertility in our cohort was the
194 need for extensive adhesiolysis during initial surgical management ($p = 0.004$). We
195 hypothesized that pelvic adherence could be responsible for decreased fertility in some
196 patients, especially as patients with uterine malformations usually undergo several
197 operations. Tubal infertility resulting from multiple surgical procedures occurred in
198 only 2 patients (20%) and this does not allow us to further confirm our assumption.

199 In patients with blind hemivagina, reflux menstruation induced by hematocolpos
200 could lead to endometriosis as supported in one the latest theories on the origin of
201 endometriosis. In our cohort, 13 patients (16.5%) were diagnosed with endometriosis
202 and is in accordance with the range reported in literature (14 - 16%) [12,13].

203 Many studies have highlighted the benefit of early surgical management in this setting
204 [5,14]. Candiani et al. reported increased fertility following surgery in patients with
205 bicorporeal uterus [15]. Indeed, early drainage of the hematocolpos induced by blind
206 hemivagina is a determinant element to prevent long-term complications such as
207 dysmenorrhea, chronic pelvic pain or dyspareunia [16]. Thus, infertility in some patients
208 with bicorporeal uterus and blind hemivagina could be partly explained by
209 endometriotic lesions, just as much as in general healthy population.

210 Although diagnostic laparoscopy is considered to be the gold standard for patients with
211 uterine malformations, recent developments in new ultrasonography techniques,
212 especially three-dimensional (3D) and contrast ultrasonography, question the need for
213 systematic laparoscopy. Faivre et al. reported that 3D ultrasonography has greater
214 sensitivity than laparoscopy or hysteroscopy for detecting uterine malformations [2].
215 Moreover, most of the patients of our cohort were successfully diagnosed by 2D -
216 ultrasonography and only 20 (25.3%) required an MRI to confirm diagnosis. As we
217 acknowledge laparoscopy was valuable in some cases, especially for assessing the pelvic
218 consequences of hematocolpos or endometriosis, we feel imaging pre operative work up
219 should be the standard of care in 2019 and laparoscopy should be reserved for
220 therapeutic management only.

221 We confirmed previous reports that patients with bicorporeal uterus and blind
222 hemivagina do not have an increased rate of early miscarriage [6,9] There are no
223 guidelines to indicate preventive cervical cerclage in these patients and it would seem

224 unnecessary in most cases. However, we do recommend close cervical monitoring
225 during early pregnancy. In our cohort, only two pregnancies (4.1%) resulted in a second
226 trimester miscarriage which is in line with recent reports concluding that this
227 malformation has no impact on the rate of second trimester miscarriages [6,8].

228 Around half of the patients delivered by caesarean section which is lower than the rates
229 reported to date (between 70 to 84%) [7]. Our decision to perform a caesarean section
230 was solely based on obstetrics factors and was not systematic. Few centres are familiar
231 with obstetric management of patients with rare uterine malformations and it is
232 possible some caesarean sections are performed as a matter of course rather than by
233 true indication.

234 As reminded in introduction, the association of bicorporeal uterus, blind
235 hemivagina and ipsilateral renal agenesis is well known [3]. This could explain the
236 higher incidence of preeclampsia in this specific population. While the association
237 between renal agenesis and preeclampsia has been previously identified [17], we were
238 unable to further confirm this association in our cohort as we had only four cases
239 (11.4%) of pregnancy - induced hypertension / preeclampsia,.

240 The retrospective nature of our study limits the quantity of data available for
241 analysis. However, we report more than 20 years of experience in treating patients with
242 bicorporeal uterus and blind hemivagina in a tertiary referral gynaecological
243 department. While, the survey response rate might seem to be low, studying fertility in
244 patients with a rare uterine malformation is difficult since most patients are diagnosed
245 and initially managed at a young age and the outcomes cannot be assessed for many
246 years. In this context, therefore, our study with a follow up of 16 years is relevant and, to
247 the best of our knowledge, constitutes one of largest cohorts ever reported. Among the
248 patients we managed to contact, a non-negligible proportion reported that they had no

249 desire to become pregnant. While this reduced the number of patients available for
250 analysis, it is also an interesting observation. These patients often undergo multiple
251 surgical procedures and experience difficult psychological conditions which could result
252 in a reluctance in attempting to get pregnant. Eventually, on a statistical point of vu, the
253 size of our cohort remains limited and it is highly possible that the association we found
254 between pelvic sepsis and post partum haemorrhage is only chance. To limit the risk of
255 describing false association between our outcomes and initial management, we limited
256 our analyses to univariate models.

257

258

259 Conclusion

260 The current retrospective study with 16 years of follow up, shows that fertility
261 seems to be conserved in patients with bicorporeal uterus and blind hemivagina and
262 that the rate of adverse pregnancy outcomes is not higher than in the general
263 population. Further studies are required to investigate which factors, such as adhesions,
264 could explain the infertility experienced by some of the patients. Eventually, we reaffirm
265 the need for patients with specific uterine malformations to be managed directly in
266 appropriate tertiary referral centres whenever possible or in collaboration with one if
267 not in order to improve both outcome and our knowledge.

268

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270

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322

323 **Table 1: Initial characteristics of the patients included**

324

	N = 79
Age at initial diagnosis (years)	16.6 (\pm 4.14)
Symptoms leading to initial diagnosis	
<i>Dysmenorrhea</i>	45 (57)
<i>Menometrorrhagia</i>	19 (25)
<i>Pelvic sepsis</i>	12 (15.2)
<i>Pregnancy</i>	2 (2.5)
<i>Infertility</i>	2 (2.5)
<i>Urinary tract infection</i>	1 (1.3)
<i>Dyspareunia</i>	1 (1.3)
Urinary tract malformations associated	
<i>Unilateral renal aplasia</i>	73 (92.4)
<i>Renal digenesis</i>	2 (2.5)
<i>Renal duplicity</i>	2 (2.5)
Initial imaging exams	
<i>Ultrasonography</i>	70 (88.6)
<i>MRI</i>	20 (25.3)
<i>Hysterosalpingography</i>	6 (7.6)
<i>CT - scan</i>	12 (15.2)
<i>Intravenous Urography</i>	10 (12.7)
<i>Abdominal X - ray</i>	5 (6.3)
<i>3D - ultrasonography</i>	2 (2.5)

325 Data are given as mean (\pm standard deviation) or as n (%)

326 MRI = Magnetic Resonance Imaging; CT - scan = Computed Tomography scan

327

328

329 **Table 2: Initial surgery and pathological analysis**

330

	N = 79
Type of surgery	
<i>Exploratory laparoscopy</i>	74 (93.7)
<i>Laparotomy</i>	13 (16.5)
Gestures performed	
<i>Vaginal unification</i>	65 (82.3)
<i>Hemihysterectomy</i>	10 (12.7)
<i>Unilateral salpingectomy</i>	6 (7.6)
<i>Drainage of an hematocolpos</i>	21 (26.6)
<i>Adhesiolysis</i>	14 (17.7)
<i>Fimbrioplasty</i>	3 (3.8)
<i>Cervix stomatoplasty</i>	4 (5.1)
Postoperative complications	8 (10.1)
Mean length of hospitalisation (days)	2.6 (\pm 2.87)
Pathological findings	
<i>Adenosis</i>	58 (73.4)
<i>Dysplasia / Cancer</i>	0 (0)
<i>Endometriosis</i>	3 (3.8)

331

332 Data are given as mean (\pm standard deviation) or as n (%)

333

334 **Table 3: Pregnancy outcomes in patients with live births**

335

	N = 35 living births
Mode of delivery	
<i>Caesarean section</i>	19 (54.3)
<i>Vaginal delivery</i>	14 (40.0)
<i>Unknown</i>	2 (5.7)
Complications	
<i>Prematurity < 37 weeks of amenorrhea</i>	7 (20)
<i>Breech presentation</i>	5 (14.3)
<i>Gravid Pregnancy - Induced Hypertension / Preeclampsia</i>	4 (11.4)
<i>Post-partum haemorrhage</i>	3 (8.6)

336

337 Data are given as n (%)

338

339 **Table 4: Initial management and predictive factors of infertility and pregnancy**
 340 **outcomes in univariate analysis.**
 341

	Infertility p-value	Number of pregnancies p - value	Live birth p - value	Second semester miscarriage p - value	Post-partum haemorrhage p - value
Laparotomy	0.6	0.18	0.12	1	1
Hemihysterectomy	0.26	0.15	0.38	1	1
Unilateral salpingectomy	1	1	1	1	1
Pelvic sepsis	1	1	1	1	0.02
Adhesiolysis	0.004	0.38	0.55	1	0.27
Drainage of an hematocolpos	0.14	1	1	1	0.49
Fimbrioplasty	0.25	1	1	1	0.15
Cervix stomatoplasty	1	1	1	0.05	0.15

342

343

344

345 **Figure caption**

346

347 **Figure 1:** Flow chart of the fertility and pregnancy survey

