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Hybrid room: Does it offer better accuracy in the proximal deployment of infrarenal aortic endograft?

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1 **Abstract**

2 **Purpose** This work aims to evaluate the impact of hybrid rooms and their advanced tools on
3 the accuracy of proximal deployment of infrarenal bifurcated endograft (EVAR).

4 **Methods** A retrospective single centre analysis was conducted between January 2015 and
5 March 2019 including consecutive patients that underwent EVAR. Groups were defined
6 whether the procedure was performed in a hybrid operating room (HOR group) or using a
7 mobile 2D fluoroscopic imaging system (non-HOR group). The accuracy of the proximal
8 deployment was estimated by the distance (mm) between the bottom of the lowest renal
9 artery (LwRA) origin and the endograft radiopaque markers parallax (LwRA/EDG distance)
10 after curvilinear reconstruction. The impact of HOR on the LwRA/EDG distance was
11 investigated using a multiple linear regression model. A composite “proximal neck”-related
12 complications event was studied (Cox models).

13 **Results** Overall, 93 patients (87 %male, median age 73 years) were included with 49 in the
14 HOR group and 44 in the non-HOR group. Preoperative CTA analysis of the proximal neck
15 exhibited similar median length, but different median aortic diameter ($p=0.012$) and median
16 beta angulation ($p=0.027$) between groups. The median LwRA/EDG distance was shorter in
17 the HOR group (multivariate model, $p=0.022$). No difference in “proximal neck”-related
18 complications was evidenced between the HOR and non-HOR groups (univariate analysis,
19 $p=0.620$).

20 Median follow-up time was respectively 25 [14-28] and 36 months [23-44] in the HOR group
21 and in the non-HOR group ($p<0.001$).

22 **Conclusion** HOR offer more accurate proximal deployment of infrarenal endografts, with
23 however no difference in “proximal neck”-related complications between groups.

24 Key words: hybrid room, EVAR, proximal seal, image fusion, endograft deployment

25 **Introduction**

26 Endovascular aneurysm repair (EVAR) has become the most frequent treatment modality for
27 infrarenal abdominal aortic aneurysm (AAA) (1). Nevertheless, it appears that the initial
28 lower morbidity and mortality compared to open surgery is not sustained when considering
29 long-term follow-up of randomised control trials (2,3). Long-term outcomes are closely
30 related to the initial anatomical conditions and meeting the eligibility criteria of the devices,
31 both merged into the instructions for use (IFU)'s book proposed by the manufacturers
32 (4,5,6,7). Proximal type 1 endoleaks (type IA) after EVAR represent the main cause of late
33 rupture (8,9,10,11).

34 Recent advances in Hybrid operating Rooms (HOR) include software that assists in
35 endovascular navigation during the procedure. In addition to the well-known fusion
36 software, that overlays the live fluoroscopy to the preoperative computed tomography
37 angiogram (CTA) or the intraoperative cone beam computed tomography (CBCT), other tools
38 such as orthogonal rings can also be manually or semi-automatically generated and added
39 on the fusion mask to delineate anatomical zones of interest. The dissemination of use and
40 access to HOR has already proven benefit for patients and medical staff in terms of radiation
41 dose exposure, amount of iodine contrast injected and subsequent procedural duration
42 (12,13,14,15); it also might reduce the number of additional endograft components
43 implanted and enable immediate intraoperative correction when necessary (12).

44 In our centre, most EVAR procedures have been performed in a HOR (IGS 730 Discovery, GE
45 Healthcare) since October 2012 incorporating a fusion mask and more recently integrated
46 orthogonal rings.

47 This work aims to compare the accuracy of the proximal deployment of infrarenal bifurcated
48 endograft completed with 2 different imaging systems, one with HOR including the

49 dedicated above-mentioned software and one mobile imaging system with no advanced
50 navigation software in a high-volume aortic centre.

51 **Methods**

52 *Study group*

53 Consecutive EVARs performed in a single tertiary referral centre from January 2015 to March
54 2019 was retrospectively included. Only patients with an available preoperative CTA
55 (completed less than 6 months prior to the procedural time) and with slice thickness lower
56 than 3mm were included. All patients had a CTA within the first 6 months postoperatively
57 after EVAR.

58 Complex aortic aneurysms (thoraco-abdominal, para or juxta-renal aneurysms) treated with
59 fenestrated and/or branched endograft, and aortic dissection were excluded from the study.

60 All EVAR procedures were performed by the same surgical team. Groups were
61 retrospectively defined according to the imaging system used for the procedure; for infra-
62 renal aortic exclusion, the choice of the operating environment is randomly assigned
63 depending on the HOR availability. The complex aortic exclusions are systematically
64 performed in the HOR

65 This study was approved by the local Institutional Ethics Review Board.

66

67

68 *Preoperative imaging*

69 Pre and post-operative CTAs were analysed on a 3D workstation (iNuition Aquarius 3D
70 Workstation TeraRecon Inc, San Mateo, Calif, USA) by the same operator trained in EVAR
71 planning. Aortic and branch vessels centerline of flow (CLF) was automatically generated and

72 modified if required. Anatomical characteristics of the infrarenal proximal neck were
73 measured (outerwall proximal and distal diameters, length, alpha and beta angles, thrombus
74 and calcifications percentage and thickness), as well as other anatomical variables (see
75 appendix for method of measurements) were also recorded. All measurements were
76 performed according to published reporting standards (16). In some situations the target
77 sealing zone can be a straight aortic segment that is not just below the lowest renal artery
78 but no patient had this aortic neck presentation and the intended sealing zone was located
79 as close as possible to the lowest renal artery in all patients.

80

81 *CTA image fusion and orthogonal rings– HOR procedures*

82 Before the index EVAR the preoperative CTA was systematically loaded onto a dedicated
83 workstation connecting to the imaging system of our HOR (Advantage Windows, GE
84 Healthcare, Chalfont, UK) (EA-AW). The workstation includes dedicated software (*EVAR*
85 *ASSIST*) that generates automatically a 3D volume rendering (VR) reconstruction with aortic
86 and branch vessels CLF. Then, following those centrelines, circles named “orthogonal rings”
87 can be drawn at the discretion of the operator to delineate anatomical regions of interest
88 (arterial bifurcation, arterial lesion, sealing zones, etc.). These rings are in the orthogonal
89 axis of the centrelines. Before the EVAR procedure, 2 orthogonal rings are drawn in order to
90 be as precisely matched to the intended point of deployment of the leading edge of the
91 endograft as possible: the first ring is drawn just below the bottom of the origin of the
92 lowest renal artery (LwRA) and the second one delineates the LwRA ostium. Then, the best
93 working projection is defined as the perpendicular plan of those 2 orthogonal rings (Figure 1)
94 and the angulation of the simulated gantry is recorded for the procedure.

95 In addition, before completing the deployment of the proximal endograft, the position of the
96 gantry can be adjusted and lined up to the orthogonal plan formed by the proximal markers
97 of the endograft that is often slightly different after the stiff wires are introduced and a new
98 angiogram can be performed to ensure accurate positioning (17).

99 Systematic meticulous analysis of the anatomy with delineation of the ‘best working
100 projection’ is done preoperatively on a dedicated workstation; whatever the imaging system
101 used afterwards

102 *Surgical procedure*

103 The hybrid endovascular suite in our institution (Discovery IGS 730, GE Healthcare, Chalfont
104 St Giles, UK) is equipped with a 30x30 centimetres flat panel detector and an EA-AW console
105 with the Innova Vision 2[®] software allowing CTA image fusion process. In this HOR, all EVAR
106 are controlled intraoperatively with a CBCT and a completion angiogram or with a contrast-
107 enhanced-CBCT. The standard fluoroscopic 2D imaging system is a mobile X-ray image
108 intensifier (OEC 9900 Elite GE Healthcare) with a floating table (STILLE, Se). All the bifurcated
109 endografts implanted during the period of the study were Zenith Low Profile[®] (LP), Zenith
110 Alpha[®] or Zenith Flex[®](Cook INC, Bloomington, IN, USA).

111 *Data collection*

112 Population characteristics, intraoperative data, perioperative management and follow-up
113 included rates of early (<30-day) and late (> 30-day) adverse events and secondary
114 interventions were reported. Intraoperative data included: endografts characteristics,
115 intraoperative preplanned and unplanned additional procedures, operating time, iodinated
116 contrast volume injected, radiation dose (Gy.cm²), fluoroscopy time and intraoperative

117 adverse events (defined as type I/III endoleaks, endograft kink or occlusion, target vessels
118 coverage, access vessels complications).

119 *Postoperative imaging*

120 All patients had a postoperative CTA (slice thickness lower than 3 mm). The postoperative
121 CTA was performed within the first month following EVAR in the non-HOR group, or sooner
122 if a complication was suspected (in both groups). A contrast-enhanced ultrasound (CEUS)
123 was completed prior to discharge for all patients, then at 6 months and yearly thereafter.

124 Thirty-day postoperative CTA for patients in the HOR group was delayed to 6 months if no
125 complication were suspected on the intraoperative CBCT nor on CEUS. In the non-HOR
126 group, all patients had a postoperative CTA in the month following surgery.

127 All the postoperative CTA were analysis on a 3D workstation (Terarecon) by an experienced
128 operator in EVAR planning. The distance between the lower edge of the LwRA and the
129 proximal gold markers of the endograft was measured after CLF reconstruction. An optimal
130 positioning is defined as a LwRA/EDG distance ≤ 2 mm. Other relevant data as the maximal
131 aortic diameter, stent kinks or/and evidence of type IA endoleak were collected.

132 *Primary and secondary endpoints*

133 The accuracy of the proximal bifurcated endograft position was estimated by the distance
134 between the lower edge of the LwRA and the parallax of the proximal gold markers of the
135 endograft (LwRA/EDG distance) and was analysed between groups in a multivariate model
136 to depict any predictors.

137 Any element during follow-up related to the proximal aortic neck including early or late
138 proximal type 1 endoleak detection or additional procedure such as additional ballooning,

139 stenting or fenestrated cuff extension at this level have been combined in a composite
140 endpoint named “proximal neck” -related complications.

141

142 *Statistical analysis*

143 Continuous variables are quoted as the median (interquartile range (IQR)) and categorical
144 variables are presented as absolute numbers (percentage).

145 Comparison of demographic, pre-operative morphological and intra-operative data were
146 performed using Student’s T for continuous covariates and the Chi-square or Fisher’s exact
147 tests for categorical covariates.

148

149 First, the dependent variable “LwRA/EDG distance” was investigated through linear
150 regression models. The multivariate analysis included all variables considered significant in
151 univariate analyses ($p < 0.20$).

152 Factors associated with the dependent variable “LwRA/EDG distance” were investigated
153 through multiple linear regression (PROC MIXED in SAS®) and results are expressed as the
154 increase in LwRA/EDG distance per unit change in the explanatory variable. Univariate
155 analyses were first conducted with graphical assessment of the regression assumptions.
156 Multivariate models were then built by first including all variables considered with a p-value
157 < 0.20 in univariate analyses ($p < 0.20$) and then using a backward selection to reduce the
158 model ($p < 0.05$ threshold).

159 Because of a direct relationship between the variable “time interval between EVAR and
160 postoperative CTA” and the LwRA/EDG distance, this variable was systematically forced into

161 the multivariate model. In order to meet linearity requirements, the time was modeled as a
162 piecewise linear effect (2 linear segments with a 12-months cut-off).

163 The presence of interactions between the delay and all other variables was systematically
164 investigated.

165 The absence of collinearity was systematically verified by calculating the Variance Inflation
166 Factor.

167 Secondly, survival analyses were conducted for the occurrence of “proximal neck” -
168 related complications (PROC PHREG in SAS®). In respect to the limited number of events,
169 only the HOR/non-HOR use and the LwRA/EDG distance covariates were tested in univariate
170 analyses. Event-free survival curves were estimated by the Kaplan-Meier method and
171 compared with the log-rank test. Median follow-up time was estimated with the reverse
172 Kaplan-Meier method. Univariate Cox analyses were also performed. The log-linearity
173 assumption for continuous variables and the proportional hazard assumption were tested by
174 Kolmogorov-type supremum tests.

175 A *p*-value of <0.05 was considered as statistically significant for all analyses.

176 **Results**

177 Ninety-three patients were included, 49 in the HOR group and 44 in the non-HOR group,
178 while 826 endovascular aortic cases were performed in our center over the same period of
179 time. Demographics and anatomical characteristics are listed in Table 1. The proximal neck
180 median diameter was significantly greater in the non-HOR group (24.0mm (22.0-25.0) vs
181 22.0mm (21.0-24.0); *p*=0.012), whereas the median beta angle was superior in the HOR
182 group (31.5° (15.5, 43.0) vs 22.0° (13.0, 30.0); *p*=0.027). The two groups were comparable
183 with respect to the other anatomical variables recorded. In one patient (non-HOR group)

184 with a history of chronic renal failure requiring dialysis, the renal arteries were covered to
185 get a proper proximal seal below the superior mesenteric artery (SMA).

186 Procedural data are presented in Table 2. Median surgical time (HOR group: 82.0 min (65.0,
187 110.0) vs non-HOR group: 90.0 min (80.0, 120.0); $p>0.05$) and median radiation dose (HOR
188 group: 21.8 Gy.cm² (12.3, 49.4) vs non-HOR group: 29.0 Gy.cm² (17.3, 71.8); $p>0.05$) were
189 similar in each group, whereas median fluoroscopic time was significantly higher in the HOR
190 group (15.4 min (11.5, 25.0) vs 10.5 min (4.9, 15.4); $p=0.014$). In the HOR group, 41 Zenith
191 alpha[®] and 8 Zenith Flex[®] were implanted and in the non-HOR group 24 Zenith alpha[®], 13
192 Zenith Flex[®] and 7 Zenith LP[®] were implanted.

193 Most of pre-planned additional procedures were unilateral or bilateral iliac branch devices
194 (n=10, all for patients in the HOR group), and endograft bifurcation kissing stenting (2 in the
195 HOR group and 4 in the non-HOR group). A patient with a low accessory renal artery origin
196 from the infrarenal aorta had a single chimney graft (HOR group). Intraoperative adverse
197 events were not different between the two groups (HOR group: n=3 (6.1%) vs non-HOR:
198 group n=4 (9.5%); $p=1.000$). A type IA endoleak was depicted on the intraoperative CBCT in 1
199 patient in the HOR group and immediately corrected with a Palmaz stent (Cordis, Fremont,
200 Calif) and 2 in the non-HOR group treated with adjunctive compliant balloon expansion
201 (Coda Balloon, Cook Medical, Bloomington, Indiana, USA). After initial correction, no
202 persistent type IA endoleak was depicted on the final completion angiogram.

203 The other intraoperative adverse events were access vessels issues due to percutaneous
204 closure system failure requiring open surgical repair (1 patient of the HOR group and 1 of the
205 non-HOR group), and a case of incorrect contralateral limb deployment requiring iliac limb
206 explantation through a left Rutherford-Morrison incision (non-HOR group).

207 Postoperative data are presented in Table 3. Postoperative adverse events rates (including
208 early and late adverse events) were similar in each group (HOR group: n=5 (10.2 %) vs non-
209 HOR group: n=5 (11.4 %); p>0.05). Early adverse events occurred in three patients including
210 one acute postoperative lower limb ischemia (HOR group), one acute renal failure that didn't
211 required dialysis (non-HOR group) and one groin hematoma (non-HOR group).

212 Most of the late adverse events were device thrombosis (n=6 (6.5%)), including 1 internal
213 iliac branch (HOR group), 3 iliac limbs (1 in HOR group and 2 in non-HOR group), 1 main
214 endograft body (HOR group) and 1 renal chimney graft (HOR group). Other late adverse
215 events were not device-related with 1 atherosclerotic acute lower limb ischemia (non-HOR
216 group). A type IA endoleak was depicted in 1 (2.1%) patient of the HOR group and 2 (5.3%)
217 patients of the non-HOR group during follow-up.

218

219 The median LwRA/EDG distance was 1.0 mm (0.5, 2.0) and 2.0mm (1.5, 3.5) respectively in
220 the HOR group and the non-HOR group (p<0.001). Sixty-six patients (71.0%) had an optimal
221 endograft positioning (meaning the distance LwRA/EDG ≤2mm) (HOR group: n=40 (81.6%),
222 non-HOR group: n=26 (59.1%)) on the first postoperative CTA.

223 Neck characteristics and postoperative LwRA/EDG distance of patients presenting a type IA
224 (intraoperative or during follow-up) are available in supplementary Table 1.

225 The rate of early and late secondary interventions (detailed in Table 4) was not different
226 between groups (HOR group: n=9 (18.4%) vs non-HOR group: n=5 (11.4%); p>0.05). Median
227 follow-up was 25 months (14, 28) in the HOR group and 36 months (23, 44) in the non-HOR
228 group (p<0.001).

229 In a multivariate analysis (Supplementary Table 2), it appeared that performing EVAR cases
230 in HOR was significantly correlated to a reduction in the LwRA/endograft distance with an

231 increasing factor (IF) of -0,69 mm (95% CI (-1.28-0.10); p=0.022), likewise a CTA performed
232 after 12 months from EVAR was associated with an increasing LwRA/endograft distance (IF=
233 +0.12 mm, 95% CI (0.05-0.18); p<0.001).

234 Using the Kaplan-Meier estimator the rate of freedom from “proximal-neck” -related
235 complications was 95.8% (IC95% [84.4; 98.9]) at 12 and was stable at two years due to the
236 few number of events (p=0.615 for the comparison of survival curves) (Figure 2).

237 In univariate Cox models, no significant difference was found between the HOR and non-
238 HOR groups (HR=0.636, 95%CI [0.106-3.811]; p=0.620). An initial optimal EDG positioning
239 (LwRA/EDG distance \leq 2mm) was not significantly associated with a lower rate of “proximal
240 neck”-related complications (HR=0.450, CI95% [0.052; 3.866], p=0.467).

241

242 **Discussion**

243 This study compares the accuracy of proximal bifurcated endograft positioning when EVAR
244 procedures are performed in HOR (associated with the use of image fusion and orthogonal
245 rings (HOR group)) or in operating rooms using a standard fluoroscopic 2D imaging system
246 (non-HOR group), in a high-volume aortic centre. This was estimated using the LwRA/EDG
247 distance measured on the postoperative CTA and was analyzed in a multivariate model.

248 The LwRA/EDG distance was lower in the HOR group compared to the other group after
249 adjusted multivariate analysis (IF= -0.69 mm, 95% CI (-1.28-0.10); p=0.022), but no
250 significant difference was found in the occurrence of early and late type IA endoleak
251 between groups (HR=0.636, 95%CI (0.106-3.811); p=0.620).

252 More than 2500 EVAR cases have been performed so far in our centre since the beginning of
253 our experience in 1995. The low number of patients included over the period of the study as
254 regard of the total number of patients treated with EVAR was mostly explained by the ability
255 to have access to the early postoperative CTA.

256 Since 2012, a hybrid operating room dedicated to vascular interventions has been available
257 in our institution and has become the preferred environment to perform endovascular aortic
258 repairs. Prior to 2012, all cases from whether straightforward or complex were managed
259 with a standard fluoroscopic 2D imaging system; since then, few standard cases are still
260 performed with this modality when the HOR is not available (149 EVAR cases since 2012
261 with a decreasing trend over years).

262 The maturation of the learning curve of our surgical team promotes systematic and
263 meticulous evaluation of the aortic anatomy whichever environment is used to achieve the
264 procedure.

265 The application of anatomical guidelines to select and treat patients with aortic endograft
266 influences the efficacy and durability of EVAR (4). Meticulous preoperative anatomical aortic
267 studies achieved with 3D imaging workstations is therefore mandatory to depict adequate
268 anatomy prior EVAR (18,19).

269 Despite performing this essential step, an endograft deployed a few millimetres below the
270 expected target position can result in a reduced and therefore insufficient proximal seal
271 length, less than the 15mm recommended by most of the manufacturers. This might
272 subsequently affect long-term durability. A perfect initial positioning is therefore crucial, and
273 deployment of the endograft as close as possible to the LwRA, even if the proximal sealing
274 zone length is greater than 15 mm, will optimise the wall apposition of the endograft.

275 With this in mind, the proximal and distal best working positions angulations, determined on
276 the preoperative CTA, are manually reported for the operator's use on a worksheet
277 accessible during the procedure in order to avoid parallax error in endograft deployment.

278

279 The relationship between the endograft apposition, position, and expansion in the aortic
280 neck and post-EVAR complications defined as type IA endoleak and/or caudal endograft
281 migration has previously been studied (20). Post-EVAR complications were significantly
282 associated with a change in position of the endograft fabric relative to the renal arteries over
283 time. We demonstrated that a CTA performed 12 months after EVAR was associated with an
284 increasing LwRA/EDG distance (increasing factor IF=0.12, 95% CI (0.05-0.18); $p<0.001$) which
285 may reflect a slight but significant endograft migration over time.

286 Thus, an initial accurate endograft position is important to reduce the risk of proximal leak
287 during follow-up.

288 In their series, Schuurmann et al (20) included 81 patients, treated with various brands of
289 endografts, where the LwRA/endograft distance just after the procedure was between 0 and
290 3 mm in 44%, too high (partially covering renal artery) in 30% and too low position (distance
291 >3mm) in 26% of patients. Bastos Gonçalves *et al.* (21) reported similar results with 29%
292 patients (of 131 patients included) observed as having a postoperative LwRA/endograft
293 distance of >5mm in patient treated with the Excluder endograft (W.L. Gore & Assoc,
294 Flagstaff, Ariz). These latter series did not specify whether the EVAR procedure was
295 performed in a HOR or not.

296 In the present study, the optimal endograft positioning was achieved in 94% (n=46/49) in the
297 HOR group and 75% (n=33/44) in the non-HOR group, when considering a target optimal gap
298 ≤ 3 mm below the lowest renal artery and the endograft. In the Bastos Gonçalves et al. study,
299 EVAR procedures were probably not performed in HOR as the period of inclusion was before
300 HOR generalization (from 2004 to 2011), and their results are close to our findings in the
301 non-HOR group.

302 All the bifurcated endografts implanted in the present report were Cook® devices which
303 IFU's state that the proximal gold markers are located within 2mm of the most proximal
304 aspect of the fabric. In reality these markers are probably less than 0.5mm from the most
305 proximal edge of the fabric (Figure 3), that's why in order to optimize the proximal sealing
306 we systematically intend to deploy the parallax of the markers of the proximal stent as close
307 as possible to the lower edge of the LwRA without considering that manufacturer's
308 instruction as relevant.

309 Despite a benefit in terms of endograft positioning the present comparative study has not
310 highlighted any clinical benefit of performing EVAR in an HOR on the postoperative risk of
311 type IA endoleak.

312 Intraoperative type IA endoleak was depicted in 3 cases (3.2%), adjunctive manoeuvres were
313 necessary to correct all of them with no persistent endoleak on final completion angiogram.
314 In the literature, the incidence of intraoperative type IA endoleak is probably
315 underestimated depending on whether cases are recorded before or after treatment
316 attempt (type IA endoleak are defined as persistent in this setting). Thus, the intraoperative
317 type IA endoleak rate varies from 3.3% to 22.6% in reports dealing specifically with
318 intraoperative type IA endoleaks (22,23,24).

319 The difference in LwRA/endograft distance observed between groups was not related to
320 inter-operator variability since the procedures were performed by the same surgical team,
321 strictly following the manufacturer's IFU in both groups. Schuurmann et al. (25) previously
322 described a semiautomated method for measuring the postoperative distance between the
323 LwRA and the endograft fabric and showed that low endograft deployment was more
324 frequently associated with increased infrarenal angulation. In our series, the proximal
325 endograft positioning was superior in the HOR group despite a beta angle that was
326 significantly steeper reflecting more challenging aortic anatomies in this latter group.

327 Moreover, the median proximal sealing zone length was greater in the HOR group, although
328 not statistically significant, but the LwRA/endograft distance was significantly shorter in this
329 group. In our series, a good median proximal sealing zone length was achieved in both
330 groups (HR group: 36.0 (23.0, 43.0) vs non-HR group: 30.0 (25.0, 43.0)). This reflects the
331 practice of our institution to perform EVAR only in case of favorable anatomies. We believe
332 that no compromise should be made in case of calcification/thrombus and/or irregular
333 diameters within aortic necks shorter than 15 mm. Otherwise these cases are managed with
334 fenestrated endografts or open repair.

335

336 As far as we know the comparison of the proximal positioning of an infrarenal bifurcated
337 endograft between HOR and standard fluoroscopic 2D imaging system has not been
338 reported yet.

339 Several advantages of HOR for EVAR procedures have already been demonstrated in terms
340 of radiation dose exposure, iodine contrast volume injected (13,15,26) and also in complex
341 cases to ease the endovascular navigation and the target vessels catheterization (27). For all
342 these elements, HOR represent a valuable environment to perform aortic endovascular
343 procedures.

344

345 Nevertheless, current imaging fusion software tool presents potential important flaws as the
346 software does not manage yet vessel displacement/distortions due to the rigidity of the
347 endovascular material inserted within the vessel (17,28,29). To correct this mismatch, a DSA
348 acquisition is usually performed after the insertion of the delivery system based on the
349 calculated best working position (usually with a cranial incidence) to confirm the renal artery
350 position, and then the mask and the orthogonal rings are then adjusted if necessary. After
351 the opening of the proximal bare stent and the first covered stent, the cranial incidence is
352 adjusted if necessary, to align the parallax of the gold markers. There is often a discrepancy
353 between the plan of the gold markers and the orthogonal rings placed below the LwRA. This
354 might be due as exposed above to the distortion of the anatomy and also might be
355 influenced by the orientation of the delivery system that is not always parallel to the aortic
356 centreline.

357 Despite these needed adjustments of the fusion mask and orthogonal rings, the use of 3D
358 guidance in HOR become the standard of care in our daily practice for EVAR procedures.

359 In the present report, it is of note the fluoroscopy time, radiation exposure and iodinated
360 contrast volume injection were not different between groups, but more patients in the HOR
361 received more frequently unilateral or bilateral iliac branch devices concomitantly to EVAR in
362 the HOR group.

363 Moreover, systematic CBCT were completed at the end of the procedure to assess the
364 endovascular reconstruction adding a significant amount of radiation dose and contrast
365 volume.

366

367 This study potentially shows limitations as it presents results from a retrospective and
368 monocentric experience. Groups of patients were not completely comparable toward
369 preoperative aortic anatomies, since more potential complicated EVAR cases were
370 performed in the HOR.

371 Another potential bias was the difference between groups toward the time interval between
372 EVAR and postoperative CTA, an independent factor that would affect (increase) the
373 LwRA/EDG distance, although this element was considered and thus adjusted in the
374 multivariate analysis.

375 At last, the influence of the type of delivery system of the endograft have been taken into
376 consideration although it may affect the precision of endograft placement. Anyway, we
377 believe that operator's volume with a type of endograft is a major point in endograft
378 deployment accuracy.

379

380 **Conclusion**

381 The use of image fusion-based roadmapping and orthogonal rings as markers in a hybrid
382 operating room environment during EVAR procedures promotes accurate proximal aortic
383 bifurcated endograft positioning. Characterising the subsequent clinical benefit of this would
384 require further investigations in larger cohorts.

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479 **Table/Figure legends**

480 Table 1 Demographics and preoperative morphological data of 93 patients undergoing EVAR
481 stratified by the type of imaging system used during procedure

482 Table 2 Procedural data of 93 patients undergoing EVAR stratified by the type of imaging
483 system used during procedure

484 Table 3 Postoperative data of 93 patients undergoing EVAR stratified by the type of imaging
485 system used during procedure

486 Table 4 Details of secondary interventions of 93 patients undergoing EVAR stratified by the
487 type of imaging system used during procedure

488 Figure 1

489 The best working position for proximal endograft deployment defined as perpendicular plan
490 of the orthogonal rings placed at the level of the aorta just below the lowest renal artery and
491 at the ostium of the lowest renal artery

492 Figure 2

493 Cumulative Kaplan-Meier survival estimates of freedom from "proximal neck"-related
494 complications (including early and late type IA endoleaks) of 93 patients treated in a hybrid
495 room (HOR group) or with a mobile 2D fluoroscopic imaging system (non-HOR group)

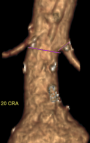
496 Supplementary Table 1 Preoperative and postoperative anatomical characteristics of
497 patients presenting an intraoperative or postoperative type IA endoleak

498 Supplementary Table 2: Multivariable associations with an increasing LwRA/EDG distance

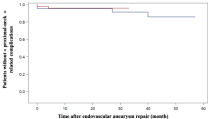
499 Figure 3

500 Location of the proximal gold markers (red arrows) of Cook® Medical bifurcated endografts
501 from the most proximal aspect of the fabric

502



TO LAO 30 CPA



No. at risk

ICR group	44	38	29	21	17	7	0
Non-ICR group	46	37	27	9	0		

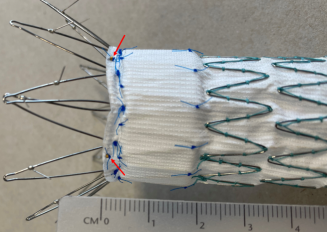


Table 1 Demographics and preoperative morphological data of 93 patients undergoing EVAR stratified by the type of imaging system used during procedure

	HOR (n=49)	Non-HOR (n=44)	Total (n=93)
Sex (female)	5 (10.2 %)	1 (2.3 %)	0.201
Age (years)	75.0 (69.0, 81.0)	71.0 (65.0, 78.0)	0.070
Previous aortic disease	1 (2.0 %)	1 (2.3 %)	1.000
Aneurysm location			0.208
Infrarenal aorta	44 (89.8 %)	43 (97.7 %)	
Common iliac artery	5 (10.2 %)	1 (2.3 %)	
Maximal aneurysm diameter (mm)	55.0 (50.0, 62.0)	54.0 (50.5, 59.0)	0.580
Infrarenal aortic neck length (mm)	36.0 (23.0, 43.0)	30.0 (25.0, 43.0)	0.855
Target vessel for proximal positioning			0.669
Lower edge of the RRA	20 (40.8 %)	16 (36.4 %)	
Lower edge of the LRA	29 (59.2 %)	27 (61.4 %)	
Lower edge of the SMA	0 (0.0 %)	1 (2.3 %)	
Proximal edge diameter of the aortic neck (mm)	22.0 (21.0, 24.0)	24.0 (22.0, 25.0)	0.012
Distal edge diameter of the aortic neck (mm)	23.0 (21.0, 25.0)	24.0 (22.0, 25.0)	0.071
Neck features			0.065
Tubular	41 (83.7 %)	33 (76.7 %)	
Angled	3 (6.1 %)	0 (0.0 %)	
Conical	5 (10.2 %)	7 (16.3 %)	
Funnel,shaped	0 (0.0 %)	3 (7.0 %)	
Alpha angle (°)	11.0 (3.0, 20.0)	13 (8.0, 22.5)	0.875
Beta angle (°)	31.5 (15.5, 43.0)	22.0 (13.0, 30.0)	0.027
Circumferential calcification percentage (aortic neck)			0.131
<25%	35 (71.4 %)	25 (56.8 %)	
25.50%	12 (24.5 %)	12 (27.3 %)	
>50%	2 (4.1 %)	7 (15.9 %)	
Circumferential thrombus percentage (aortic neck)			0.376
<25%	38 (80.9 %)	34 (82.9 %)	
25.50%	8 (17.0 %)	4 (9.8 %)	
>50%	1 (2.1 %)	3 (7.3 %)	

HOR: Hybrid operating room, LRA: left renal artery, non-HOR: mobile 2D fluoroscopic imaging system RRA: right renal artery, SMA: superior mesenteric artery patient with chronic renal failure requiring dialysis, renal arteries were covered

Continuous data are presented as the median (Inter Quartile Range) and categorical data as counts (percentage)

Table 2 Procedural data of 93 patients undergoing EVAR stratified by the type of imaging system used during procedure

	HOR (n=49)	Non-HOR (n=44)	<i>p</i>
Emergent cases*	3 (6.1 %)	1 (2.3 %)	0.619
Access vessels			<0.001
Percutaneous approach	38 (77.6 %)	7 (15.9 %)	
Surgical cutdown	9 (18.4 %)	37 (84.1 %)	
Both	2 (4.1 %)	0	
Operating time (min)	82.0 (65.0, 110.0)	90.0 (80.0, 120.0)	0.879
Fluoroscopy time (min)	15.4 (11.5, 25.0)	10.5 (4.9, 15.4)	0.014
Radiation dose (Gy.cm ²)	21.8 (12.3, 49.4)	29.0 (17.3, 71.8)	0.325
Iodinated contrast volume (mL)	70.0 (57.0, 80.0)	80.0 (60.0, 100.0)	0.343
Intraoperative endovascular additional procedures	16 (38.3%)	9 (22.0%)	0.097
<i>Preplanned</i>			
Unilateral iliac branch device	8 (16.3%)	0	
Bilateral iliac branch devices	2 (4.1%)	0	
Endograft bifurcation kissing stenting	2 (4.1%)	4 (9.1%)	
External iliac artery stenting	1 (2.0%)	2 (4.5%)	
Internal iliac artery embolisation	0	1 (2.3%)	
Renal chimney	1 (2.0%)	0	
<i>Unplanned</i>			
Iliac limb endograft extension	1 (2.0%)	0	
Proximal seal palmaz stenting	1 (2.0%)	0	
Proximal seal compliant balloon expansion	0	2 (4.5%)	
Intraoperative adverse events	3 (6.1%)	4 (9.1%)	1.000
Type IA endoleak	1 (2.0%)	2 (4.5%)	
Type IB endoleak	1 (2.0%)	0	
Access vessels issues	1 (2.0%)	1 (2.3%)	
Iliac limb extraction	0	1 (2.3%)	

HOR: Hybrid operating room, non-HOR: mobile 2D fluoroscopic imaging system

Continuous data are presented as the median (Inter Quartile Range) and categorical data as counts (percentage)

* symptomatic or ruptured aneurysm

Table 3 Postoperative data of 93 patients undergoing EVAR stratified by the type of imaging system used during procedure

	HOR (n=49)	Non-HOR (n=44)	<i>p</i>
Early and late adverse events	5 (10.2 %)	5 (11.4 %)	1.000
Postoperative CTA analysis			
Time from procedure to postoperative CTA (months)	5.0 (0.0, 9)	1.0 (0.0, 9.5)	0.442
Slice thickness \leq 1mm	38 (77.6 %)	32 (74.4 %)	0.725
CTA with arterial phase	41 (83.7 %)	35 (81.4 %)	0.774
Difference in diameter compared to preoperative CTA (mm)	0 (. 1, 2)	0 (-1, 2)	0.951
Type IA endoleak	1 (2.1 %)	2 (5.3 %)	0.581
Kink	2 (4.1 %)	1 (2.3 %)	1.000
LwRA/EDG distance* (mm)	1.0 (0.5, 2.0)	2.0 (1.5, 3.5)	0.001
Early and late secondary interventions	9 (18.4 %)	5 (11.4 %)	0.346
Follow-up (months)	25 (14, 28)	36 (23, 44)	<0.001
LwRA/EDG distance	HR (n=49)	Non-HR (n=44)	Total (n=93)
\leq 2 mm	40 (81.6%)	26 (59.1%)	66 (71.0%)
2-4 mm	7 (14.3%)	14 (31.8%)	21 (22.6%)
\geq 5mm	2 (4.1%)	4 (9.1%)	6 (6.5%)

HOR: Hybrid operating room, non-HOR: mobile 2D fluoroscopic imaging system

Continuous data are presented as the median (Inter Quartile Range) and categorical data as counts (percentage)

* distance between the LwRA (Lowest renal artery) and endograft (EDG) measured on postoperative CTA after aortic curvilinear reconstruction

Table 4 Details of secondary interventions of 93 patients undergoing EVAR stratified by the type of imaging system used during procedure

	Indication	Time from procedure
HOR group (n=49)		
Iliofemoral bypass (n=1)	Acute lower limb ischemia	6 days
Groin hematoma drainage (n=1)	Groin hematoma	16 days
Iliac limb thrombectomy (n=1)	Iliac limb occlusion	2 months
Palmaz stenting (n=1)	Type IA endoleak	4 months
Adjunctive iliac limb (n=1)	Type IB endoleak	7 months
Transcaval embolization (n=2)	Type II endoleak	8 and 24 months
Surgical endograft explantation (n=1)	Endograft occlusion	13 months
Fenestrated cuff (n=1)	Thoraco-abdominal aneurysm	19 months
Non-HOR group (n=44)		
Translomber embolization (n=1)	Type II endoleak	13 months
Iliac limb thrombectomy (n=1)	Iliac limb occlusion	19 months
Common femoral endarterectomy (n=1)	Chronic limb ischemia	25 months
Crossover femorofemoral bypass (n=1)	Iliac limb occlusion	39 months
Fenestrated cuff (n=1)	Type IA endoleak	43 months

HOR: Hybrid operating room, non-HOR: mobile 2D fluoroscopic imaging system