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Initial Results of Antegrade Laser Fenestrations Using Image Fusion Guidance and Company Manufactured Stent Grafts in Complex Aortic Aneurysm Repair

Jean Sénémaud, Guillaume Fadel, Joseph Touma, Vania Tacher, Marek Majewski, Frédéric Cochenec, Hicham Kobeiter, Pascal Desgranges

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1 **Title:** Initial results of antegrade laser fenestrations using image fusion guidance and
2 company-manufactured stent-grafts in complex aortic aneurysm repair.

3 **Short title:** Aortic repair using laser-fenestrated stent-grafts

4

5 **Authors information:** Jean Sénémaud ¹ (jeannicolas.senemaud@aphp.fr), Guillaume Fadel ¹
6 (guillaumefadel@hotmail.fr), Joseph Touma ¹ (joseph.touma@aphp.fr), Vania Tacher ²
7 (vania.tacher@aphp.fr), Marek Majewski ¹ (marek.majewski@aphp.fr), Frédéric Cochenec ¹
8 (frederic.cochennec@aphp.fr), Hicham Kobeiter ² (hicham.kobeiter@aphp.fr), Pascal
9 Desgranges ¹ (pascal.desgranges@aphp.fr).

10 ¹ Centre Hospitalier Universitaire Henri Mondor, Department of Vascular Surgery, 51 avenue
11 du Maréchal de Lattre de Tassigny, Créteil, France.

12 ² Centre Hospitalier Universitaire Henri Mondor, Medical Imaging Service, Interventional
13 and Therapeutic Vascular and Oncologic Radiology Unit, 51 avenue du Maréchal de Lattre de
14 Tassigny, Créteil, France.

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18 **Corresponding author:** Pr. Pascal DESGRANGES

19 E-mail: pascal.desgranges@aphp.fr

20 Tel: +331 49 81 24 25

21 Present address: Service de Chirurgie Vasculaire et Endocrinienne, Centre Hospitalier
22 Universitaire Henri Mondor, 51 avenue du Maréchal de Lattre de Tassigny, 94010 Créteil,
23 France.

24 **What this paper adds:** The principal limitation of custom-made devices is the long
25 manufacturing and shipping delay, precluding their use in symptomatic or large aneurysms. In
26 such features, laser-fenestrated stent-grafts could be an alternative. This paper describes the
27 first series including mid-term follow-up of physician-modified stent-grafts using antegrade
28 laser fenestrations and image fusion guidance (LEVAR) for the treatment of complex
29 abdominal aortic aneurysms, thoracoabdominal aortic aneurysms and type I endoleaks. The
30 12-month overall survival and target vessel patency rates were acceptable at the cost of very
31 frequent intraoperative adverse events and significant reinterventions rates, requiring close
32 and extensive follow-up.

33 ABSTRACT

34 **Objectives:** To describe initial outcomes of physician-modified stent-grafts using antegrade
35 laser fenestrations and image fusion guidance (LEVAR) and company-manufactured custom-
36 made stent-grafts (CM) for the treatment of complex abdominal aortic aneurysms (CAAAAs),
37 thoracoabdominal aortic aneurysms (TAAAs) and type I endoleaks (T1ELs).

38 **Design:** Retrospective single center study.

39 **Methods:** All LEVAR and Zenith (Cook) CM procedures between January 1st, 2012 and
40 December 31st, 2018 were reviewed. Endpoints included intraoperative adverse events
41 (IOAEs), in-hospital mortality, reinterventions, target vessels patency and 12-month outcomes
42 (overall survival, freedom from reintervention, target vessel patency). Outcomes at 12 months
43 were estimated using the Kaplan-Meier method.

44 **Results:** A hundred patients were identified and included in the study. All patients were
45 deemed unfit for open repair. The cohort included 22 LEVAR and 78 CM. LEVAR cases
46 included painful aneurysms (n=5), >65 mm aneurysms (n=10), anatomical constrains and/or
47 presence of previous renal stents (n=7) or cases declined by the manufacturer planning center
48 (n=2). IOAEs were recorded in 41% of cases (n=9) in the LEVAR group versus 10% (n=8,
49 p=.002) in the CM group. The rate of in-hospital mortality in the LEVAR group was 9%
50 (n=2) versus 4% (n=3, p=.30) in the CM group. The median follow-up duration was 22
51 months (7-38) in the LEVAR group and 28 months (11-78) in the CM group. The estimate of
52 overall survival at 1 year was 91% in both groups. The freedom from reintervention rate at 1
53 year was 58% in the LEVAR group versus 87% in the CM group. The target vessel patency
54 rates at 1 year were 95% in both groups.

55 **Conclusion:** In high-risk patients deemed unfit for open repair, LEVAR may provide
56 satisfactory 12-month overall survival and target vessel patency rates, though reported rates of

57 IOAEs, mortality and reinterventions rates were high thus requiring close and extensive
58 follow-up.

59

60 **Key words:** aorta, aneurysm, laser fenestrations, image fusion guidance, stent-graft.

61

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63 commercial, or not-for-profit sectors.

64

65 **Conflict of interests:** None

66 **MANUSCRIPT**

67 **INTRODUCTION**

68 The use of manufactured custom-made stent-grafts (CM) for the treatment of complex
69 abdominal aortic aneurysms (CAAAAs) and thoracoabdominal aortic aneurysms (TAAAs) has
70 gained widespread acceptance, especially in high-risk patients unfit for open repair ^[1]. The
71 principal limitation of CM devices is the long manufacturing and shipping delay, precluding
72 their use in symptomatic or large aneurysms. In such cases, endovascular alternatives include
73 CHIMPS (CHIMney, periscope and snorkel techniques) ^[2], “off-the-shelf” devices ^[3] and
74 physician-modified stent-grafts ^[4] which all have the advantage of being immediately
75 available. In situ antegrade fenestration of stent-grafts could be of interest in cases in which a
76 CM device is not possible or available in patients precluded from open repair. A recent report
77 has described antegrade laser fenestration using preliminary target vessel stenting, in order to
78 enhance target vessels guidance, for the treatment of CAAAs and TAAAs ^[5]. Potential major
79 hindrances of the technique include fenestrations accuracy and target vessel catheterization,
80 along with the reno-visceral ischemia induced by the temporary coverage of target vessels.

81 The objectives of the present report were to describe the 12-month results of laser fenestrated
82 endovascular aortic repair using image fusion guidance (LEVAR) without preliminary
83 stenting and custom-made stent-grafts for the treatment of CAAAs, TAAAs and type I
84 endoleaks (T1ELs) in high-risk patients.

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88

89 **METHODS**

90 **Study population and technical features**

91 This study is a single-center, retrospective study. All consecutive patients presenting with
92 CAAAs, TAAAs, and T1ELs undergoing endovascular repair using custom-made fenestrated
93 Zenith devices (Cook Medical Inc, Bloomington, In., USA) or LEVAR technique between
94 January 1st, 2012 and December 31st, 2018 in our center were included. The inclusion began
95 January 1st, 2012 for the CM group and September 1st, 2016 for the LEVAR group. The date
96 of last follow-up collection was December 1st, 2019.

97 CAAAs included juxtarenal and suprarenal aneurysms. TAAAs were classified according to
98 the modified Crawford classification ^[6]. Patients were precluded from open or hybrid repair
99 during a multidisciplinary weekly review board including vascular surgeons, interventional
100 radiologists, and anesthesiologists. Patients were considered as high-risk i.e. unfit for open
101 repair following the Haute Autorité de Santé (HAS, French health-care regulation agency)
102 criteria namely the patient age, history of coronary artery disease, congestive heart failure,
103 chronic obstructive pulmonary disease, renal function impairment and hostile abdomen. The
104 American Society of Anesthesiologists (ASA) and Metabolic Equivalent of Task scores were
105 also taken in consideration. Our experience of LEVAR began September 1st, 2016. Indications
106 of LEVAR included painful aneurysms, rapidly enlarging > 65 mm aneurysms considered as
107 having a high risk of rupture, type I endoleaks after previous EVAR, presence of anatomical
108 limitations (i.e. neck<10mm length or aortic neck diameter >34mm) and/or previous renal
109 stent placement precluding the use of a CM device and cases declined by the manufacturer
110 planning center. Rapidly enlarging aneurysms were defined as a > 5mm growth within 6
111 months assessed by computerized tomography angiogram (CT).

112 All patients underwent CT scan within 3 months preoperatively and within 1 month after the
113 operation. The follow-up included clinical examination and CT scans every six months.

114 This study was conducted according to the principles of the Helsinki II declaration. Informed
115 written consent was obtained from all patients. The study was approved by the local
116 Institutional Review Board (Henri Mondor University Hospital IRB). Potential risks and
117 benefits of LEVAR and CM stent-grafts were discussed in detail. The theoretical increased
118 risk of procedure failure, endoleaks and reinterventions associated with LEVAR along with
119 the lack of standardization and long-term data were clearly explained.

120 Demographic features (such as gender, age, coronary artery disease, chronic kidney disease,
121 chronic obstructive pulmonary disease, diabetes mellitus, smoking status, and American
122 Society of Anesthesiologists score), intraoperative and post-operative data were prospectively
123 recorded in a dedicated database. Operative details included median time to surgery (i.e. from
124 referral date to surgery date), number of target vessels intended for treatment, amount of
125 contrast medium, procedure and fluoroscopy durations and ischemia duration per target vessel
126 during LEVAR procedure. Intraoperative adverse events (IOAEs) included any unplanned
127 complication occurring during stent-graft implantation including target vessel loss,
128 cannulation failure, target vessel injury, stent kink, iliofemoral complication and type I/III
129 endoleaks. Postoperative data included 30-day and in-hospital mortality/complications,
130 reinterventions (i.e. any procedure occurring after the index date of operation related to the
131 stent-graft, target vessels, aorto-iliac or lower limbs segments), target vessel patency,
132 endoleaks and 1-year outcomes. Complications were classified according to Society for
133 Vascular Surgery standards ^[7]. Postoperative kidney injury was defined using the RIFLE
134 criteria ^[8]. Spinal cord ischemia was defined as occurrence of temporary or definitive
135 postoperative paraparesis or paraplegia. Paralysis was defined as the inability to walk
136 independently and paraparesis was defined as a weakness associated with the ability to walk

137 independently. If spinal cord ischemia occurred postoperatively, emergent lumbar
138 cerebrospinal fluid (CSF) drainage using an intrathecal catheter was performed in order to
139 obtain a CSF pressure ≤ 12 mmHg along with a mean blood pressure between 78 and 85
140 mmHg.

141 Usual guidelines were used to define endoleak type ^[9]. The outcomes evaluated at 6 months
142 included overall survival, reinterventions, and target vessel patency.

143 Procedure planning and device sizing were performed using a dedicated 3D vascular imaging
144 workstation (Aquarius NetStation; Tera Recon, San Mateo, CA, USA) with centerline luminal
145 reconstructions. Custom-made fenestrated stent-grafting procedures were performed either in
146 an angiography suite (Allura Xper FD20, Philips Healthcare, Best, The Netherlands) or in an
147 operating room equipped with a Philips Veradius C-arm. Juxtarenal, suprarenal and type IV
148 thoracoabdominal aortic aneurysms were treated during a single step procedure when using
149 CM device. For extended TAAAs, our strategy was to stage repair whenever possible. All
150 patients with type I, II, III and V TAAAs underwent preventive CSF drainage in the cohort.

151

152 **Image fusion guidance**

153 All LEVAR procedures were performed in an angiography suite (Allura Xper FD 20)
154 equipped with 3DA and XperCT options. Image guidance details were described in previous
155 publications of our group ^[10]. Briefly, immediately before intervention, the preoperative CT
156 images were loaded into a dedicated 3D-workstation (XtraVision Release 8, Philips
157 Healthcare) to be coupled with the peroperative cone-beam computed tomography (CBCT)
158 images. A 3D roadmap was created and overlaid on the 2D-fluoroscopy, providing the
159 projection of the target vessels, which ostia were represented by rings (Figure 1). Such
160 landmarks were used to select the optimal C-arm angulation during endovascular navigation.

161 The accuracy of image fusion guidance (IFG) was assessed at the beginning of each
162 intervention: a 0.035” guidewire was placed into the left renal artery and was used as a
163 landmark, allowing an eventual correction of a mismatch between preoperative and CBCT
164 images.

165

166 **Laser fenestration procedure (Figure 1)**

167 All procedures were performed under general anesthesia. Intravenous heparin was
168 administrated (100 UI/kg) and the activating clotting time was monitored to be over 250
169 seconds during the procedure. Laser fenestrations were performed through Endurant
170 bifurcated endografts (Medtronic, Santa Rosa, CA, USA), proximal Endurant aortic
171 extensions (Medtronic) or Valiant endografts (Medtronic) depending on the proximal aortic
172 landing zone level and aortic coverage length required. The stent-graft was deployed using
173 IFG with a proximal sealing zone of 30 mm. A 22 mm or 28 mm Aptus Heli-FX guide
174 (Medtronic) was used as a steerable sheath for the 0.9 mm Turbo Elite laser catheter coupled
175 to the CVX300 system (Spectranetics, Colorado Springs, USA). Antegrade fenestrations of
176 the stent-graft were performed using the laser probe during 2 to 3 seconds (wavelength of 810
177 nm, 14-18 Watts ^[11]). A 0.014” microcatheter (Pilot 0.014, Abbott, Chicago, USA) was used
178 after laser perforation to catheterize the target vessels. A 2.5 mm cutting balloon (Boston
179 Scientifics, Marlborough, USA) and a 4 to 5 mm semi-compliant balloon (Viatic, Abbott,
180 Chicago, USA) were then inflated to enlarge the fenestration. The first target vessel was
181 always the superior mesenteric artery (SMA) in order to limit the duration of bowel ischemia.
182 Target vessel stenting was performed using balloon-expandable covered stents implanted with
183 a 1 cm intra-aortic segment (V12 Atrium, Maquet, Rastatt, Germany). The aortic portion of
184 the bridging stent was flared using a Mustang 10 mm x 2 mm balloon (Boston Scientifics,
185 Marlborough, Massachusetts, USA). Before and after stent deployment, 5 ml of iodinate

186 contrast injections (Visipaque, Iodixanol, GE Healthcare, Cork, Ireland) ensured correct target
187 vessel catheterization and stent patency. A final angiogram and a CBCT were performed to
188 detect stent complications or endoleaks.

189 In the CM group, Advanta V12, Lifestream (Bard, Arizona, USA) and Begraft (Bentley
190 Innomed GmbH, Hechingen, Germany) devices were used as bridging stents. Each stent was
191 flared using Mustang 10 or 12 x 2 cm balloons.

192

193

194 **Endpoints**

195 Major endpoints included IOAEs, 30-day and in-hospital mortality/complications, in-hospital
196 reinterventions, target vessel patency, endoleaks and 1-year outcomes. The 1-year outcomes
197 included overall survival, freedom for aortic death, freedom from reintervention (i.e. any
198 procedure occurring after the index date of operation related to the stent-graft, target vessels,
199 aorto-iliac or lower limbs segments) and target vessel patency rates.

200

201 **Statistical analysis**

202 Perioperative outcomes were analyzed using univariable analysis. Quantitative variables were
203 reported as median and interquartile range (IQR, Q3-Q1). Categorical variables were reported
204 as numbers and percentages and compared using the Chi-square or Fisher's test when
205 appropriate.

206 All 12-month outcomes were estimated using the Kaplan-Meier time to-event method and
207 95% confidence interval. Statistical analysis was performed using SAS 9.4 (SAS Institute,
208 Inc, Cary, NC, USA). We considered the tests were significant at a p value <0.05.

209

210 **RESULTS**

211 **Cohort description**

212 Between January 1st, 2012 and December 31st, 2018, a total of 100 patients were included.
213 During the study period, 78 patients underwent fenestrated Zenith devices (Cook)
214 implantation, and 22 LEVAR procedures were performed. In this cohort, the rates of 30-day,
215 6-month and 12-month follow-up in surviving patients were of 100%, 100% and 96%
216 respectively. The median follow-up duration was 22 months (7-38) in the LEVAR group and
217 28 months (11-78) in the CM group (cohort median: 26,5 months).

218 Demographic data are detailed in **Table I**. Indications of LEVAR included painful aneurysms
219 (n=5), large (>65 mm) aneurysms which were considered as having a high risk of rupture
220 (n=10), anatomical constrains and/or presence of previous renal stents (n=7) or cases declined
221 by the manufacturer planning center (n=2). The patients presenting with painful aneurysms in
222 the LEVAR group included three type I endoleaks (with maximal aortic diameters
223 respectively of 98 mm, 60 mm and 114 mm), one tender 58mm type IV TAAA and one
224 70mm type V TAAA

225 The median maximal preoperative aortic diameter was of 59 mm (IQR: 16) in the LEVAR
226 group versus 59 mm (IQR: 6) in the CM group. Specifically, the median maximal aortic
227 diameter in the large aneurysms subgroup was of 78 mm in the LEVAR group. The LEVAR
228 group included 12 CAAAs (54%), six type I endoleaks after previous EVAR/TEVAR (27%)
229 and four TAAAs (18%). The CM group included 66 CAAAs (85%) and 12 TAAAs (15%).

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234 **Operative details**

235 Median time from first referral to surgery was of 37 +- 19 days in the LEVAR cohort versus
236 105 +- 57 days in the CM group. In the LEVAR group, the median time from referral to
237 surgery in the patients presenting with painful aneurysms and >65mm aneurysms was
238 respectively of 12 and 31 days. The total number of target vessels was of 61 in the LEVAR
239 group and 241 in the CM group. The number of target vessels per patient was 2.8 +- 0.7 in the
240 LEVAR group vs 3 +- 0.9 in the CM group. In the LEVAR group, the target vessels were
241 intended to be catheterized either through laser fenestrations (n = 55) or using open chimneys
242 (n = 6). Laser fenestrations were performed on 13 bifurcated Endurant II (Medtronic), five
243 Valiant (Medtronic) thoracic stent-grafts, three Endurant aortic extensions and one aorto-uni-
244 iliac Medtronic device. In the LEVAR group, the median ischemic time for the SMA was of
245 22 minutes, of 48 and 58 minutes for the renal arteries and of 70 minutes for the celiac artery.
246 All LEVAR procedures took place in an angiography suite. In the CM group, patients
247 underwent device implantation either in the angiography suite (n=50) or under C-arm control
248 (n=28).

249 Intraoperative adverse events were reported in 41% of cases in the LEVAR group (n=9) and
250 in 10% (n=8) in the CM group (p= .002, **Table II**). Though the stent-graft fabric was
251 successfully perforated in all cases in the LEVAR group, two renal arteries could not be
252 catheterized because of significant proximal renal artery stenosis, leading to a catheterization
253 success rate of 97% (n= 59/61). In the LEVAR group, one renal artery was lost during the
254 procedure secondary to a dissection that could not be recovered. In another patient of the
255 same group, the inability to catheterize the renal artery required a bailout chimney stenting
256 using brachial access with favorable renal function outcome. In the LEVAR group, additional

257 target vessel stenting was required in five cases (27%) either for target vessel kink observed
258 after primary stenting (n=3, 17%) or for correction of a target vessel dissection (n=2, 11%).

259

260 **In-hospital outcomes**

261 Postoperatively, two patients died in the LEVAR group (9%) versus three (4%) in the CM
262 group (p=.30, **Table III**). In the LEVAR group, a 68-year-old patient presenting with a 56
263 mm juxtarenal aortic aneurysm with previous history of myocardial infarction and cardiac
264 failure was treated using an Endurant stent-graft (Medtronic) to revascularize the SMA and
265 both renal arteries. As described previously, the right renal artery was lost during the
266 procedure. The patient developed a nosocomial pneumonia and died 50 days postoperatively.
267 The second death in the LEVAR group occurred in a 71-year-old patient presenting with a
268 painful 58mm type IV TAAA associated with preoperative occlusion of the right renal artery
269 and right iliac artery. She underwent an Endurant aorto uni-iliac device implantation with two
270 laser fenestrations (SMA and LRA) and a chimney stenting for the celiac artery. The
271 procedure was uneventful. The patient presented with postoperative acute right limb ischemia.
272 An emergent femoro-femoral bypass was performed, which led to a hemorrhagic shock
273 during procedure and fatal bowel ischemia at day 3 postoperatively, though the CA and SMA
274 were patent on the CT scan.

275 Complications were frequent in both groups, respectively of 41% (n=9) in the LEVAR group
276 and 28% (n=22) in the CM group (p=.30, **Table III**). No spinal cord ischemia was recorded in
277 the LEVAR group postoperative course. In the CM group, three cases (4%) of SCI occurred
278 (two transient paraparesis and one definitive paraplegia). Postoperative acute kidney injury
279 was recorded in 14% (n= 3) of LEVAR patients versus 13% in CM group (n=10). On
280 postoperative CT scans, the rate of type I endoleaks was of 8% (n=2) in the LEVAR group

281 versus 0% in the CM group and the rate of type II endoleak was of 12% in the LEVAR group
282 (n=2) versus 22% (n=8) in the CM group. No type III endoleaks were observed.

283

284

285 **In-hospital reinterventions**

286 No open conversion was described in the cohort. Postoperative reinterventions were frequent
287 in the LEVAR group (n= 7, 33% vs n= 12, 15% in the CM group, p=.12, **Table IV**). In the
288 LEVAR group, the postoperative type I endoleaks required one proximal embolization and
289 one distal extension procedure. The two stent-limb complications in the LEVAR group
290 required respectively additional one iliac stenting procedure using a Begraft stent and one
291 stent-limb extension using Endurant II limb. Additionally, two type II embolization
292 procedures were performed in the LEVAR group.

293

294 **Target vessel patency and endoleaks at discharge**

295 At discharge, no type I or type III endoleaks were recorded in the cohort. The rate of type II
296 endoleaks was 9% in the LEVAR group (n=2) versus 24% (n=19) in CM group. At discharge,
297 target vessel patency rate was 98% (n=60/61) in the LEVAR group vs 98% (n= 237/241) in
298 the CM group.

299

300 **Follow-up**

301 No death occurred during follow-up in the LEVAR group. A total of 13 patients died during
302 the follow-up in the CM group. Cases included stent-graft infection (n=1), pulmonary

303 infection (n=1), stroke (n=1), myocardial infarction (n=5), cancer (n=3) and two deaths of
304 unknown cause. No aneurysm rupture was recorded during the follow-up in the cohort. The
305 Kaplan-Meier estimate of overall survival at 1-year was 91% (CI95% 68-98) in the LEVAR
306 group vs 91% (CI95% 82-96) in the CM group (**Figure 2A**).

307 The estimate of freedom from aortic death at 1 year was of 95% (CI95% 72-99) vs 96% (CI
308 89-99) in the CM group (**Figure 2B**). Two reinterventions occurred during follow-up in the
309 LEVAR group. An external iliac stenting for significant stenosis was performed in a 63-year-
310 old patient 6 months after an uneventful LEVAR procedure for a 68mm juxtarenal aortic
311 aneurysm. Another patient, who required an antegrade bailout chimney stenting after failure
312 of renal artery catheterization during index procedure, presented with a type Ia endoleak
313 postoperatively. The persistence of a type II endoleak on the follow-up CT scan led to an
314 angiography which revealed a type Ia endoleak through the gutters of the chimney stent.
315 Embolization using Onyx liquid embolic system (Medtronic) through upper access was
316 performed with satisfactory outcome. Nine patients underwent secondary reinterventions in
317 the CM group during follow-up including additional renal artery stenting (n= 2), additional
318 SMA stenting (n=2), type II endoleak embolization (n=2), thoracic stent-graft implantation
319 (n=1), hypogastric aneurysm endovascular exclusion (n=1) and one limb occlusion. The
320 estimate of freedom from reintervention at 1-year was of 58% (CI95% 35-75) in the LEVAR
321 group vs 87% (CI95% 76-93) in the CM group (**Figure 2C**). One target vessel (celiac artery)
322 was recorded as occluded during follow-up in the CM group. Target vessel patency rates at 1
323 year were 95% in the LEVAR (CI95% 72-99) group vs 95% in the CM group (CI95% 87-98,
324 **Figure 2D**).

325

326 **DISCUSSION**

327 Our results suggest that LEVAR technique may provide satisfactory 12-month overall
328 survival and target vessel patency rates in cases in which CM are unavailable or not possible
329 for high-risk patients. The results presented in our study, reporting the largest experience of
330 antegrade laser fenestrations in aortic aneurysm repair so far, should however be interpreted
331 with caution. Indeed, various limitations of our study exist. First, we could not perform
332 propensity-matching or stratification because of the limited number of patients in the LEVAR
333 group and the important pre-surgical differences between the LEVAR and CM groups,
334 including challenging aneurysm anatomies in the LEVAR group and different timelines. This
335 impaired a statistically based comparison of initial outcomes of LEVAR and CM techniques.
336 Nevertheless, our descriptive analysis of LEVAR outcomes may be of interest since only one
337 study reported initial results ^[5] to date. Besides, such data could be used in the future if a
338 meta-analysis was to be performed. Secondly, the retrospective single-center nature of the
339 study and the small size of the LEVAR group may also limit its scope, reflecting our growing
340 experience using an off-label technique. Finally, the follow-up duration was short in the
341 cohort, requiring extensive and close patient monitoring.

342 During LEVAR procedure, the fenestrations were performed rather easily in the LEVAR
343 group using the steerable Heli-FX sheath, with a reported fenestration success rate of 100%
344 using the laser catheter and a target vessel catheterization rate of 96%. In the two cases in
345 which the renal arteries could not be catheterized though the fabric was perforated, no type IV
346 endoleaks were observed during follow-up, probably because of the small size of the
347 fenestrations which were in direct contact with the aortic wall. In our practice, we performed
348 laser fenestrations in polyethylene terephthalate stent-grafts rather than in expanded
349 polytetrafluoroethylene, the latter presenting with significant leak rate after laser fenestration
350 in an experimental study ^[12]. In the LEVAR group, the implanted stent-grafts included

351 bifurcated Medtronic devices for CAAAs and type I endoleaks and Valiant or Endurant
352 extensions for TAAAs, which required more aortic coverage. The Valiant stent-graft allowed
353 rather easily laser fenestrations and target vessel catheterization because of its monofilament
354 structure and the spacing between the nitinol struts.

355 Compared to standard imaging, the IFG could theoretically enhance the accuracy of target
356 vessel catheterization, thus limiting the number of laser fenestrations attempts and the risk of
357 type IV endoleaks. Compared to preoperative target vessels stenting ^[5], the use of IFG could
358 shorten the procedure and limit contrast agent and fluoroscopy duration along with procedure
359 costs ^[13]. However, such potential benefits are to be balanced with the risk of target vessel
360 injury illustrated in our series; Indeed, nearly half of the patients in the LEVAR group
361 presented with IOAEs and 23% required additional target vessel stenting. Specifically, five
362 patients in the LEVAR group required additional SMA or renal stenting during the index
363 procedure because of target vessel dissection or the presence of a kink at the distal edge of the
364 bridging stent. Though such complications are not specific of LEVAR technique, they could
365 be explained by the absence of reducing ties in the stent-grafts used in the LEVAR group and
366 by the small gap between the stent-graft and the target vessels ostia resulting in challenging
367 target vessel catheterization and stenting. Such complications represent our current experience
368 and an area for improvement, contrasting with the absence of such events in the CM group.
369 Moreover, postoperative complications and early reinterventions were more frequently
370 reported in the LEVAR group, though without reaching statistical significance.

371 In the LEVAR group, the 58%-low freedom from reintervention rate during follow-up may be
372 considered as a potential Achille's heel of the technique, being more important compared to
373 fenestrated CM repair in our center. Such results may be explained by the more frequent
374 postoperative endoleaks reported in the LEVAR group and by the operators learning curve,
375 our experience with LEVAR beginning in September 2016 in contrast of CM repair which

376 began in 2006. Though reinterventions were frequent in the cohort, no open conversion or
377 aneurysm rupture were reported during follow-up and target vessel patency rates were
378 satisfactory at 12 months in both groups.

379 Various options exist in the settings of patients unfit for open repair for CAAAs and TAAAs
380 treatment. The use of CHIMPS techniques in CAAAs was proven effective ^[2] but may induce
381 type I endoleaks, especially when more than two chimneys are deployed ^[14] as it is the case in
382 TAAAs. Physician-modified devices using manual fenestrations may also be an interesting
383 option ^[4, 15] but are considered as challenging procedures and require very precise
384 planification. One of the major theoretical advantage of the LEVAR in aortic repair is the
385 freedom from long manufacturing delays and costly custom-made devices. Indeed, LEVAR
386 only requires the laser specific material and standard stent-grafts and could generate reduced
387 costs compared to CM devices. In terms of consumables, the cost of a LEVAR procedure for
388 a juxtarenal aneurysm represents the half of a CM intervention. Indeed, the specific material
389 required for a LEVAR procedure includes an Endurant bifurcated endograft (3000 to 4000
390 euros), a 22- or 28-mm steerable catheter (1500 euros), the laser probe (1000 euros), 0.014”
391 microcatheters, 2.5 mm cutting balloons and 4 to 5 mm semi-compliant balloons, giving an
392 approximative cost of 7500 euros (after depreciation of the CVX-300 Excimer laser system).
393 In contrast, CM repair includes the fenestrated device, a bifurcated stent-graft, and extensions
394 for an approximative total cost of 16 000 euros. However, this should be assessed by a cost-
395 effectiveness evaluation which was out of the scope of our study. LEVAR might also be an
396 interesting option in cases of anatomical contraindications of CM devices. The usefulness of
397 IFG during LEVAR procedures lies in its accuracy ^[16] and the absence of target vessels
398 deformation, allowing optimal catheterization. Le Houérou et al. have described the use of
399 preliminary target vessel stenting before LEVAR procedure for complex aortic repair ^[5]. The
400 potential pitfalls of preliminary stenting include potential risk of target vessels injury and

401 increased amount of contrast agent and radiation exposure. Besides, preliminary stenting may
402 be a more costly procedure compared to IFG because of the two-step procedure and extended
403 duration of stay.

404 However, to date, the LEVAR technique does not represent a valid treatment for standard
405 repair of CAAAs, TAAAs or T1ELs. LEVAR procedure remains a complex, unstandardized
406 technique requiring precise planning, experienced physicians and heavy endovascular gear
407 which should be performed in dedicated high-volume centers ^[17]. In our practice, LEVAR
408 procedures are indicated for few selected cases, i.e. high-risk patients too frail for open repair
409 and cases unfit for CM devices. Nevertheless, the high rates of IOAEs, postoperative
410 complications and reinterventions highlight the need for caution when performing LEVAR
411 procedures and demand close follow-up. Moreover, the lack of mid-term data of this “off-
412 label” technique induces major concerns about target vessel patency, endoleaks and aneurysm
413 sealing during follow-up, requiring extensive follow-up duration. The main drawback of
414 LEVAR technique according to some physicians is the target vessel ischemic duration since
415 the technique implies a temporary coverage of the reno-visceral arteries before laser
416 fenestrations. First, we always started the procedure using a 0.035” guidewire in the SMA
417 using antegrade approach. In our experience, the SMA fenestrations rate was of 100% and we
418 did not perform bailout procedures. Secondly, during LEVAR procedure, the SMA
419 fenestration was performed first in order to limit bowel ischemia. Finally, we report ischemic
420 times of 22 minutes for the SMA and less than an hour for renal arteries. We report one case
421 of bowel ischemia in the LEVAR group, but it occurred in the settings of a hemorrhagic
422 shock, the celiac artery and SMA being patent on the postoperative CT scan. Concerning
423 renal ischemic durations, we report a rate of postoperative acute kidney injury of 14% in the
424 LEVAR group, similar to rates reported in another series including LEVAR procedures ^[5],
425 though comparison should be cautious. It is likely than refinement of the LEVAR technique

426 might improve initial results. In our practice, we usually use a graft oversizing of 15-20% but
427 the use of under-sized grafts in the visceral aorta might be of interest. The use of reducing tie
428 stent-grafts might could also theoretically limit renovisceral ischemia.

429 The second main drawback of LEVAR technique is the off-label and un-reinforced
430 fenestrations. Indeed, the potential risk of endoleak secondary to the stent-graft puncture and
431 its enlargement by the cutting-balloons is critical. An experimental study suggested that laser
432 fenestration technique was more prone to cause type III endoleak compared to mechanical
433 fenestrations, since fenestrations are not reinforced when using the laser technique ^[12]. In our
434 early experience, we did not notice postoperative type III or IV endoleaks in the LEVAR
435 group though endoleaks were frequently reported. Long-term durability of LEVAR technique
436 in aortic aneurysm repair will directly depend on the biomechanical constrains and device
437 fatigue, thus requiring extensive follow-up and additional experimental and clinical data.

438

439 **CONCLUSIONS**

440 Our study suggests that LEVAR technique may provide satisfactory 12-month overall
441 survival and target vessel patency rates in the settings of high-risk patients deemed for open
442 repair. Reported rates of intraoperative adverse events, mortality, complications, and
443 reinterventions were high in the LEVAR group. The high rates of reinterventions and the
444 theoretical risk of postoperative endoleak secondary to LEVAR procedures require close and
445 extensive follow-up. Additional experimental and clinical data are required to assess the
446 validity and the safety of LEVAR for aortic aneurysm repair in dedicated high-volume
447 centers.

448

449 **CONFLICT OF INTEREST STATEMENT**

450 Authors do not have conflict of interest to declare.

451

452 **ACKNOWLEDGMENTS**

453 None.

454

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511

512

513 Copy editors: please note that only the critical style editing has been made to these tables. Full
 514 copy editing (including setting up italics vs non-italics and indenting) is still needed. I have
 515 used green background color to highlight the edits that should be repeated in the following
 516 rows in the same column.

517 **TABLE I. Demographics and comorbidities of 100 patients** treated for complex aortic aneurysm by
 518 custom-made (CM) or laser-fenestrated stent-graft (LEVAR).

520
 521

	<i>LEVAR n=22</i>	<i>CM n=78</i>	<i>Overall n=100</i>
Median age, median (IQR) – y	71 (11)	73 (13)	73 (13)
Men	17 (77)	65 (83)	82 (82)
Comorbidities			
<i>Diabetes mellitus, n (%)</i>	2 (9)	16 (20)	18 (18)
<i>Smoking history, n (%)</i>	13 (59)	54 (76)	67 (67)
<i>Hypertension n, (%)</i>	19 (86)	68 (87)	87 (87)
<i>Coronary artery disease, n (%)</i>	6 (27)	34 (43)	40 (40)
<i>History of myocardial infarction, n (%)</i>	6 (27)	20 (26)	26 (26)
<i>Congestive heart failure, n (%)</i>	2 (9)	22 (28)	24 (24)
<i>History of stroke, n (%)</i>	6 (27)	12 (15)	18 (18)
<i>Chronic renal insufficiency, n (%)</i>	7 (32)	32 (41)	39 (39)
<i>COPD, n (%)</i>	6 (27)	25 (32)	31 (31)
<i>Obesity, n (%)</i>	5 (23)	8 (10)	13 (13)
<i>History of cancer, n (%)</i>	3 (14)	9 (11)	12 (12)
<i>Peripheral arterial disease, n (%)</i>	11 (50)	5 (6)	16 (16)
<i>History of aortic surgery, n (%)</i>	10 (45)	11 (14)	21 (21)
ASA Score			
<i>Asa 2</i>	2 (9)	18 (23)	20 (20)

<i>Asa 3</i>	17 (77)	42 (54)	59 (60)
<i>Asa 4</i>	3 (14)	17 (22)	20 (20)

522

523 *Data are presented as n (%) unless stated otherwise.*

524 ASA: American Society of Anesthesiologists (ASA)

525 COPD: chronic obstructive pulmonary disease

526 IQR: interquartile range (Q3-Q1)

527

528 *Note that in Table 2, in addition to other edits, the additional rows need to be created (an*
 529 *example shown in green).*

530 **TABLE II: Intraoperative details of 100 patients treated for complex aortic aneurysm by**
 531 **custom-made (CM) or laser-fenestrated stent-graft (LEVAR).**
 532

	LEVAR (n=22)	CM (n=78)	Overall (n=100)	p
<i>Mean procedure duration (IQR) - min</i>	176 (60)	206 (70)	199 (70)	
<i>Mean fluoroscopy duration (IQR) - min</i>	73 (30)	65 (35)	70 (35)	
<i>Mean contrast medium (IQR) - mL</i>	87 (40)	112 (60)	104 (55)	
<i>Patients presenting with IOAE</i>	9 (41)	8 (10)	17 (17)	.002
<i>Intraoperative deaths</i>	0	0	0	
<i>Open Conversion</i>	0	0	0	
Target Vessel Loss, n (%)	1/61 (2)	4/241 (2)	5/302	
<i>Cannulation failure, n (%)</i> - -	2 (9)	3 (4)	5 (5)	
<i>Requiring bailout procedure</i>	1	1		
<i>Requiring reintervention</i>	0	1		
Additional SMA stenting -For kink -For dissection	3 (14) 2 1	0 (0)	3 (3)	
Additional renal stenting -For kink -For dissection	2 (9) 1 1	0 (0)	2 (2)	
Additional Embolization for type I endoleak after final angiogram	2 (9)	0 (0)	2 (2)	

<i>Femoral access complication, n (%)</i>	1 (4)	5 (6)	6 (6)	533
				534

535

536

537 *Data are presented as n (%) or n unless stated otherwise.*

538 IOAE: intraoperative adverse event

539 IQR: interquartile range (Q3-Q1)

540 SMA: superior mesenteric artery

541

TABLE III. Postoperative outcomes of 100 patients treated for complex aortic aneurysm by custom-made (CM) or laser-fenestrated stent-graft (LEVAR).

	LEVAR (n=22)	CM (n=78)	Overall (n=100)	p
Mean length of stay(IQR) - d	13 (7)	12 (7)	12 (7)	
30-day mortality	1 (4)	3 (4)	4 (4)	1.0
In-hospital mortality, n (%)	2 (9)	3 (4)	5 (5)	.30
Causes of death, n (%)				
<i>Bowel/colonic ischemia</i>	1 (4)	2 (3)	3 (3)	
<i>Pulmonary infection</i>	1 (4)	0 (0)	1 (1)	
<i>Access infection</i>	0 (0)	1 (1)	1 (1)	
Patients presenting with ≥ 1 non-fatal complication, n (%)	9 (41)	22 (28)	31 (31)	.30
Total of non-fatal post-operative complications	10	29	39	
<i>Stroke</i>	0	1 (1)	1 (1)	
<i>Spinal cord ischemia</i>	0	3 (4)	3 (3)	
<i>Acute kidney injury</i>	3 (14)	10 (13)	13 (13)	
<i>Risk</i>	2	4	6	
<i>Injury</i>	0	3	3	
<i>Failure</i>	1	3	4	
<i>Bowel/colonic ischemia</i>	0	3 (4)	3 (3)	
<i>Severe acute respiratory syndrome</i>	0	3 (4)	1	

<i>Hemorrhage</i>	1 (4)	2 (3)	3 (3)	
<i>Access site infection</i>	0	2 (3)	2 (2)	
<i>Acute limb ischemia</i>	1 (4)	5 (6)	6 (6)	
<i>Stent limb complication</i> - -	2 (9)	0	2 (2)	
<i>Kink</i>	1			
<i>Preocclusion</i>	1			
<i>Type Ia endoleak</i>	1 (4)	0	1 (1)	
<i>Type Ib endoleak</i>	1 (4)	0	1 (1)	
<i>Type III endoleak</i>	0	0	0	
<i>Cerebrospinal fluid leak</i>	1 (4)	0	1 (1)	

542

543 *Data are presented as n (%) or n unless stated otherwise. IQR: interquartile range (Q3-Q1)*

544

545

546

547 **Table IV. Early reinterventions in 100 patients** treated for complex aortic aneurysm by
 548 custom-made (CM) or laser-fenestrated stent-graft (LEVAR).

	LEVAR (n=22)	CM (n=78)	Overall (n=100)	p ⁴⁹
Patient requiring reinterventions	7 (32)	12 (15)	19 (19)	.12;1
Total reinterventions	7	13	20	552
Open conversion for aneurysm rupture	0	0	0	553
Colectomy for colonic ischemia	0	1 (1)	1 (1)	554 555
Branch-related instability	0	4 (5)	4 (4)	556
<i>Target vessel injury</i>	0	1 (1)	1 (1)	557
<i>Additional CA stenting</i>	0	1 (1)	1 (1)	558
<i>Additional CA stenting for type III EL</i>	0	0 (0)	0 (0)	559
<i>Additional RA stenting for type III EL</i>	0	2 (3)	2 (2)	560
Endoleak unrelated to target vessels				
<i>Proximal embolization</i>	1 (4)	0	1 (1)	
<i>Proximal extension</i>	0	0	0	
<i>Distal extension</i>	2 (9)	0	2 (2)	
<i>Type II embolization</i>	2 (9)	0	2 (2)	
Access	2 (9)	7 (9)	9 (9)	
<i>Iliac stenting</i>	1 (4)	2 (3)	3 (3)	
<i>Femoro-femoral bypass</i>	1 (4)	1 (1)	2 (2)	
<i>Lower limb embolectomy</i>	0	3 (4)	3 (3)	
<i>Lower limb amputation</i>	0	0	0	
<i>Groin debridement</i>	0	2 (3)	2 (2)	

Data are presented as n (%)

CA: celiac artery

EL: endoleak

RA: renal artery

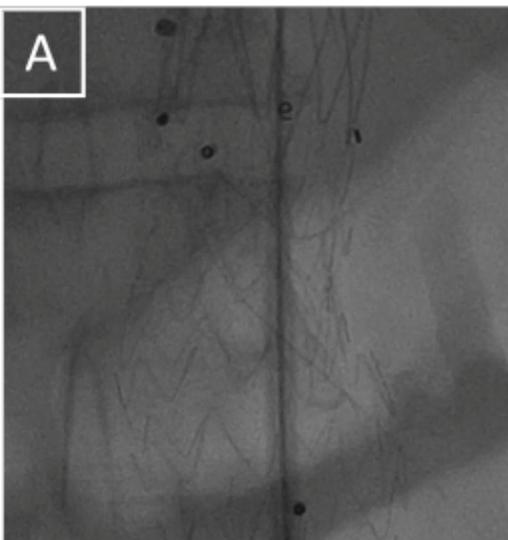
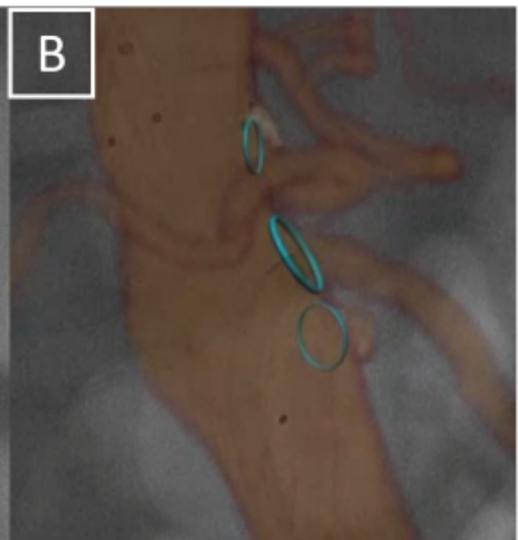
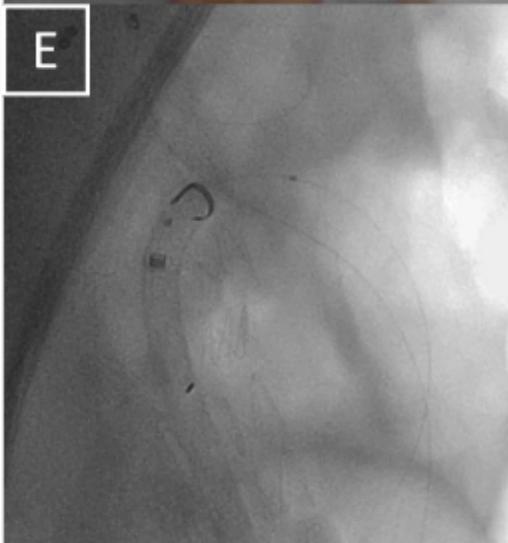
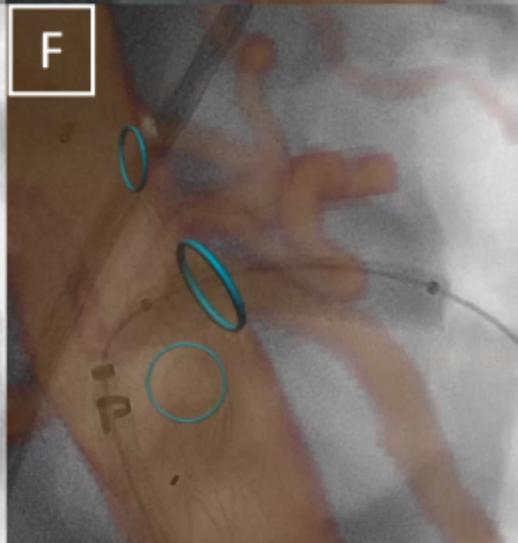
561 **FIGURES LEGENDS**

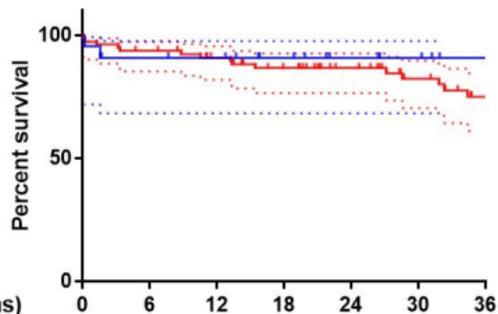
562 **Figure 1.** Antegrade laser fenestrations procedure using image fusion guidance. (A) Stent-
563 graft deployment. (B and C) Orientation of the Heli-FX sheath towards the superior
564 mesenteric artery (SMA) ostium using image fusion guidance. (D) A 0.014” guidewire is
565 positioned through the lumen of the SMA after antegrade fenestration using the Turbo Elite
566 laser catheter. € The fenestration is enlarged using a 2.5mm cutting balloon and a 4-5 mm
567 semi-compliant balloon. (F) Bridging stent deployment using a V12 Atrium balloon-
568 expandable stent.

569

570 **Figure 2.** Cumulative Kaplan-Meier estimates of). (A) overall survival,(B) freedom from
571 aortic death or, (C) reintervention, and (D) target vessel (TV) patency during follow-up after
572 treatment of complex aortic aneurysm by custom-made stent-graft (CM) or laser-fenestrated
573 stent-graft (LEVAR).

574

A**B****C****D****E****F**

A**Overall survival**

Follow-up (months)

LEVAR patients at risk (n)

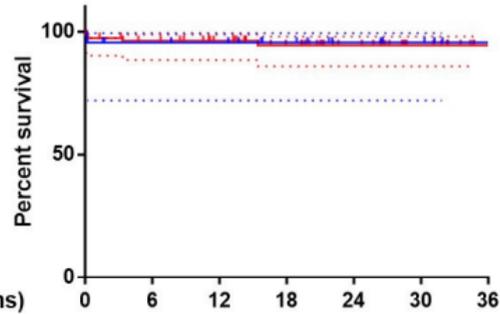
CM patients at risk (n)

0	6	12	18	24	30	36
22	20	19	15	11	9	6
78	73	66	57	47	37	29

B**Freedom from aortic death**

LEVAR

CM



Follow-up (months)

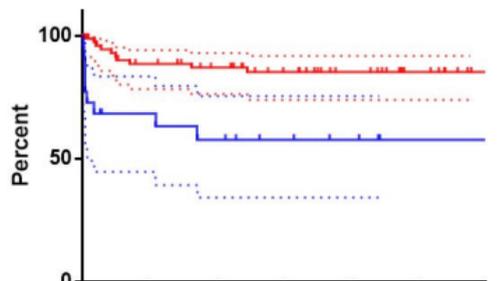
LEVAR patients at risk (n)

CM patients at risk (n)

0	6	12	18	24	30	36
22	20	19	15	11	9	6
78	73	66	57	47	37	29

LEVAR

CM

C**Freedom from reintervention**

Follow-up (months)

LEVAR patients at risk (n)

CM patients at risk (n)

0	6	12	18	24	30	36
22	14	12	9	7	4	4
78	59	53	44	36	28	21

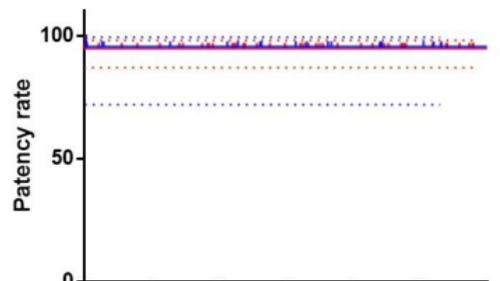
LEVAR

CM

D**Target vessel patency**

LEVAR

CM



Follow-up (months)

TV at risk (LEVAR, n)

TV at risk (CM, n)

0	6	12	18	24	30	36
61	57	30	27	24	18	10
241	220	195	171	138	109	80

LEVAR

CM