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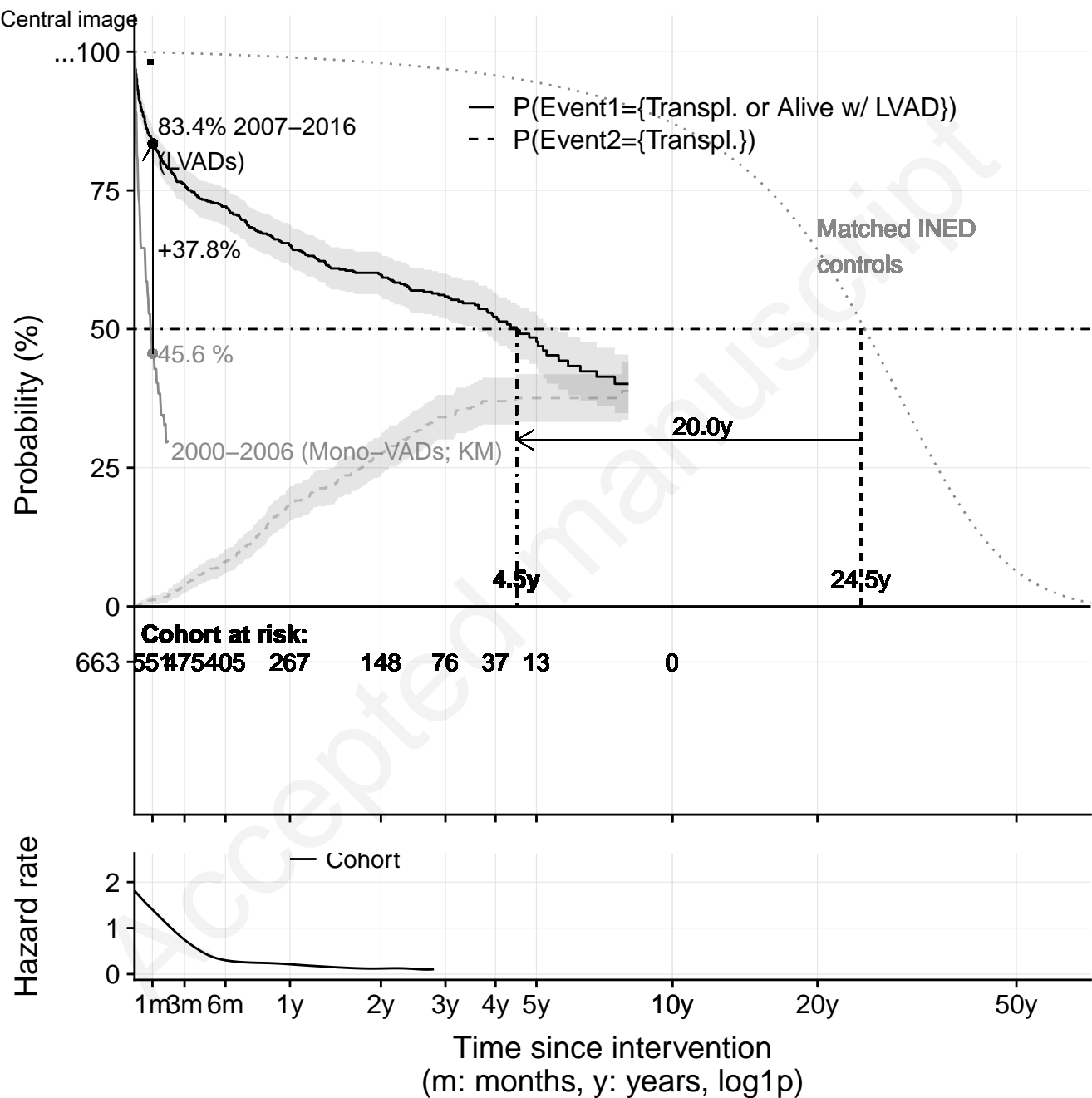
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# **CURRENT RESULTS OF LEFT VENTRICULAR ASSIST DEVICE THERAPY IN FRANCE: THE ASSIST-ICD REGISTRY**

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On behalf of the Determination of Risk Factors of Ventricular Arrhythmias  
After Implantation of Continuous Flow Left Ventricular Assist Device  
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79 **Abstract**

80 **Objective.** Provide a picture of LVAD activity in France between 2007 and 2016 based on  
81 the multicentric ASSIST-ICD Registry.

82 **Methods.** We retrospectively collected 136 variables including in-hospital data, follow-up  
83 survival, and adverse events over N=671 LVAD recipients at 20 out of 24 LVAD-implanting  
84 centers in France. The average follow-up was 1.2 years (SD: 1.4) and the total follow-up  
85 was 807.5 patient-years.

86 **Results.** The included devices were HeartMate II®, HeartWare LVAS® or Jarvik 2000®.  
87 The overall likelihood of being alive under LVAD support or transplanted (primary  
88 endpoint) at 1-, 2-, 3- and 5-years post-implantation was 65.2%, 59.7%, 55.9%, and  
89 47.7%, given a cumulative incidence of being transplanted at year 5 of 29.2%. At  
90 implantation, 21.5% of patients were on ECLS. The overall rate of cardiogenic shock at  
91 implantation was 53%. The major complications were driveline infection (26.1%), pump  
92 pocket or cannula infection (12.6%), LVAD thrombosis (12.2%), ischemic (12.8%) or  
93 hemorrhagic stroke (5.4%; all strokes 18.2%), noncerebral hemorrhage (9.1%), and LVAD  
94 exchange (5.2%). The primary endpoint (survival) stratified by age at surgery and by type  
95 of device employed, with inference from baseline profile. The primary endpoint combined  
96 with an absence of complications (secondary endpoint) also stratified by device type.  
97 **Conclusions.** The ASSIST-ICD registry provides a real-life picture of LVAD use in 20 of  
98 the 24 implanting centers in France. Despite older average age and higher proportion of  
99 destination therapy patients, survival improved as compared to previous national registry  
100 results. This LVAD registry contrasts with other international registries as implanted  
101 patients are more severe and national policy for graft attribution is distinct. We recommend  
102 to refer LVAD patients earlier and suggest to discuss the optimal transplantation timing e  
103 of bridged patients (more dismal results after the second year of support?).

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107 **KEYWORDS:** Left Ventricular Assist Devices; Outcomes; Temporal Trends

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## **Introduction.**

While heart transplantation remains the gold standard treatment for end-stage heart failure, long-term mechanical circulatory support (MCS) emerged as a viable option both for bridge-to-transplant patients and patients not amenable to transplantation. Following the encouraging results of first generation devices [1], second generation Continuous-Flow Left Ventricular Assist Devices (CF-LVADs) improve on survival and functional status [2]. In this context, the group for reflection on mechanical circulatory assistance (GRAM, *Groupe de Réflexion sur l'Assistance Mécanique*) published in 2011 a landmark report over MCS in France over the 2000-2005 period [3]. Later, the ASSIST-ICD registry was setup to investigate ventricular arrhythmias under CF-LVAD in France between 2007 and 2016. However, this registry turned out to also be a unique appraisal of LVAD activity throughout France between 2007 and 2016, even though it wasn't conceived as a follow-up to the GRAM database. As a result, based on the ASSIST-ICD registry, we herein provide trends, results, and specificities of LVAD therapy in France with respect to previous data and international practice.

## 136 **Patients and Methods.**

### 137 Data collection and management of the ASSIST-ICD registry

138 ASSIST-ICD (determination of risk factors of ventricular arrhythmias (VAs) after  
139 implantation of continuous flow left ventricular assist device) is an observational,  
140 retrospective, single-cohort, multi-center registry. Initially, it was conceived to help  
141 decision-making in arrhythmology and cardiac electrophysiology by studying late  
142 ventricular arrhythmias, survival, death causes, indications, effectiveness, and implantable  
143 cardioverter defibrillator (ICD) therapy complications in LVAD patients.

144 The registry includes patients aged 18 or older at implantation, primary-implanted  
145 between January 2007 and December 2016, and with one of three CF-LVADs, i.e.,  
146 HeartMate II (Abbott Inc., Chicago, IL), HeartWare HVAD (Medtronic Inc., Minneapolis,  
147 MN), or Jarvik 2000 LVAD (Jarvik Heart Inc., New York, NY). The registry excludes  
148 patients having a total artificial heart, a pulsatile LVAD, having any device other than those  
149 mentioned above, and being heart transplanted before LVAD support.

150 The ASSIST-ICD register was approved by local ethical committees, the French advisory  
151 committee on the treatment of research data in healthcare, and France's data protection  
152 authority (CNIL, *Commission Nationale de l'Informatique et des Libertés*). It is recorded as  
153 NCT02873169 in the ClinicalTrials.gov database. As required by French authorities for  
154 retrospective studies, we collected non-opposition letters from patients. Over 24  
155 cardiothoracic centers implanting LVADs in adult patients in France, 20 (83%) contributed  
156 to the registry. In this report, as compared to our previous publication [4], our analysis  
157 features herein one more center (Marie Lannelongue Hospital).

158 The registry describes patients with 136 pre-, intra-, and post-operative variables, which  
159 we collected retrospectively from hospital records. According to each center's protocol, we  
160 conducted follow-up through outpatient visits and recurrent hospitalizations (if applicable).  
161 Individual teams managed antithrombotic therapy under LVAD. Multidisciplinary teams

162 performed systematic follow-up according to local organizational settings. The study's  
163 latest follow-up was December 31<sup>st</sup>, 2016.

164

#### 165 Left Ventricular Assist Devices

166 As mentioned previously, included patients received one of three CF-LVADs, i.e.,  
167 HeartMate II, HeartWare HVAS, or Jarvik 2000 LVAD. We've included patients irrespective  
168 of the surgical approach, i.e., median sternotomy, left posterolateral thoracotomy, or left or  
169 right mini invasive thoracotomy. We also bring up that reimbursement policy between  
170 devices did not differ, that implanting teams were free to choose the device in each case,  
171 and that there's no formal recommendation to choose between LVAD types in France. We  
172 describe the number of LVAD implanted per year and per model in Figure 1.

173

#### 174 Endpoints

175 In this report, as transplantation competes with survival under LVAD, we primarily report  
176 results on the event: being alive under LVAD support or transplanted (i.e., not dying under  
177 LVAD support), thereby focusing the analysis on the patient's long-term outcome. Then,  
178 we define the secondary endpoint as the composite event: having no major complication  
179 and, the primary endpoint, being alive under LVAD or transplanted. The third endpoint  
180 illustrates recent national trends in CF-LVAD therapy. We define early outcomes as  
181 occurring within the 30<sup>th</sup> post-operative day or later (if during the same hospitalization). We  
182 include all later events in the follow-up analysis.

183

#### 184 Statistical Analysis

185 We describe continuous data with the mean and the standard deviation (SD). We report  
186 counts and proportions for categorical and ordinal data. For continuous variables we test



187 for differences using the Mann–Whitney U test. For categorical or ordinal variables we use  
188 the Chi-Squared or the Fisher's Exact test when a cell-count is less than 5.

189 To describe death etiology we report actual frequency estimates. Given the competing  
190 risk of transplantation, we estimate the primary endpoint's probability (alive under LVAD  
191 support or transplanted) as the complement of the cumulative incidence of dying under  
192 LVAD support. We compute instantaneous hazard rates for primary and secondary  
193 endpoints with Epanechnikov's kernel function and a local-bandwidth at each grid-point.

194 To compare cumulative incidence per group we use the log-rank test. To visualize  
195 survival evolution by era, next to our cohort's primary endpoint (LVAD-only; N=671) we  
196 overlay Mazzucotelli et al.'s cohort survival (mostly left mono-VADs; N=133) [3]. We draw  
197 up that few transplantations have occurred yet in that early period, thereby allowing us to  
198 neglect the influence of the competing risk due to transplantation. We also compare our  
199 cohort against the lifetable's expected survival, matched for gender, age, and intervention-  
200 year, from the French institute for demographic studies (INED). In this case we use the  
201 one sample log-rank test [4]. Statistical analyses are done with R 3.5.0.

202

## 203 **Results.**

### 204 Early Results

205 Between 2007 and 2016, N=671 patients received an LVAD at the 20 French centers,  
206 which represents 33 (SD: 3.9) devices per center in average. While 25% percent of the  
207 centers implanted all three devices, 45% implanted two, and 30% used only one. Table 1  
208 depicts the pre-implantation characteristics of the registry.

209 Our registry has 70.5% of HeartMate II, 18.9% of HeartWare, and 10.6% of Jarvik 2000.  
210 In average, LVAD-patients staid 25.8 days (SD: 50.9) at the intensive care unit (ICU) and  
211 50.9 days (SD: 37.1) at the hospital. We infer that LVAD-recipients often had severe  
212 cardiogenic shock before LVAD implantation, because 29.2% had at least one modality of

213 transient MCS (ECLS, IABP, or Impella) and 21.5% had ECLS. Average levels of serum  
214 creatinine (129.8  $\mu\text{mol/L}$ ) and blood bilirubin (23.2 mg/dL) suggest severe patient profiles  
215 having variable degrees of end-organ failure. To manage severe right ventricular  
216 dysfunction, 12.5% of the patients had early ECLS after LVAD implantation and temporary  
217 right heart MCS. Hospital mortality at 30 days is 16.6% (SD: 1.9) mortality. Figure 2  
218 details the study's flowchart.

219

### 220 Follow-up results

221 We observe an average follow-up duration of 1.2 years (SD: 1.4) with 807.5 patient-  
222 years available for analysis and no patient lost at follow-up. Estimates of the primary  
223 endpoint (alive under LVAD support or being transplanted) at 1-, 2-, 3- and 5 years after  
224 implantation are 65.2%, 59.7%, 55.9%, and 47.7% respectively. The central Figure  
225 illustrates the primary endpoint probability in the overall cohort along with the hazard rate.  
226 Hazard is greatest during the three postoperative months, but after six months it plateaus  
227 until the end of the second post-implantation year when it increases again.

228 As compared to the previous GRAM report [3], whose patient survival for the  
229 univentricular assistance cohort is overlaid in the central Figure, our patient's early survival  
230 (30 days) under LVAD increased dramatically from 45.6% to 83.4%. Nevertheless, due to  
231 the severity of cardiovascular diseases in advanced heart failure patients, the registry's  
232 median life expectancy is 20 years lower ( $p < 0.001$ ) than France's national life table.

233 In terms of death etiology, the registry records 130 cases of cardiac deaths (19.4%) of  
234 which we consider 55 (8.2%) right ventricular failures, 31 (4.6%) LVAD thromboses, 22  
235 (3.3%) malignant ventricular arrhythmia, 3 (0.4%) cardiac tamponade, and 3 (0.4%) LVAD  
236 failures. In terms of extracardiac deaths, the registry totals 13 (1.9%) deaths due ischemic  
237 stroke, 35 (5.5%) due to hemorrhagic stroke, 19 (2.8%) due to other hemorrhage, 8 (1.2%)

238 due to mesenteric ischemia, 5 (0.7%) due to respiratory insufficiency, 48 (7.1%) due to  
239 septic shock, 15 (2.2%) due to multiorgan failure, and 4 (0.6%) due to other causes.

240 In terms of LVAD-related complications, as reported in Table 2 the registry records  
241 driveline (26.1%) and pump pocket or cannula infections (12.7%), LVAD thromboses  
242 (12.5%), ischemic (12.8%) and hemorrhagic strokes (5.5%—all strokes rate 18.2%), TIA  
243 (0.9%), noncerebral hemorrhages (12.8%), and LVAD exchange (5.2%). The six reasons  
244 for LVAD exchange are LVAD thrombosis (62.9%), LVAD dysfunction (14.3%), LVAD  
245 cannula infection (5.7%), aortic thrombosis (2.9%), LVAD cannula displacement (2.9%),  
246 and other reasons (11.4%). In average the delay from LVAD implantation to LVAD  
247 thrombosis was 7.6 months, to first stroke was 3 months, and to first bleeding was 4.1  
248 months. During follow-up 196 patients (29.2%) received heart transplantation. The  
249 average time between LVAD implantation and heart transplant was 150 days (4.9 months).

250 Figure 3 Panel C shows that age at implantation (less than 54, between 55 and 64, older  
251 than 65) affects the likelihood of being alive under LVAD or transplanted ( $p < 0.001$ ), with  
252 youngest patients having the best outcome. Hazard rates suggest that the risk increase in  
253 older individuals is essentially driven by the first six post-implantation months.  
254 Subsequently, hazard rates are similar until they increase again after the second post-  
255 implantation year, notably for older patients. The latter increase is likely due to the greater  
256 fragility of older patients, which leads to more complications under support and  
257 complication-related mortality.

258 Figure 3 Panel D suggests significant differences per device type ( $p < 0.001$ ), with  
259 HeartMate II recipients presenting better likelihood of being alive under LVAD or  
260 transplanted than HeartWare HVAS and Jarvik 2000 recipients. However, recipient  
261 characteristics differ significantly between device types, e.g., the average age at  
262 implantation is 57.3 years for HeartMate II recipients, 56.7 for HeartWare HVAD, and 62.5  
263 for Jarvik 2000 ( $p < 0.01$ ), while indication as destination therapy is 33.6% for HeartMate II,

264 37.8% for HeartWare HVAD, and 74.6% for Jarvik 2000 ( $p<0.01$ ). Additionally, these  
265 differences subtend the survival disadvantage associated with no option for transplantation  
266 and, likely, heterogeneous degrees of baseline comorbidities among subgroups. Figure 3  
267 Panel E suggests a mild difference between LVAD types for the secondary endpoint, i.e.,  
268 being alive under LVAD, transplanted, and having no major complication ( $p=0.015$ ) but,  
269 like previously, age or indication tend to confound the observed difference.

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## 273 **Discussion.**

274 Originally, the ASSIST-ICD registry aimed to rationalize the use of implantable  
275 cardioverter-defibrillators in LVAD-recipients. This initial work resulted in the VT-LVAD  
276 score to predict the risk of malignant ventricular arrhythmias [5]. However, given the large  
277 adherence to this registry among French centers implanting LVADs (20 out of 24), the  
278 number of variables ( $N=136$ ), the number of patients ( $N=671$ ), and the follow-up era (2007  
279 to 2016), the ASSIST-ICD registry emerged as a picture of LVAD activity in France. We  
280 therefore discuss herein the major LVAD-related descriptors and outcomes.

281

### 282 Comparison with previous experience in France

283 Using data from the GRAM, whose important seminal work we acknowledge, a report of  
284 2011 published results about long-term mechanical circulatory assistance in France  
285 between 2000 and 2006 [3]. Here we compare our register to this earlier report.

286 Our patients are older at implantation (57.7 vs. 43.7 years) and fewer (58.4% vs. 87.9%)  
287 are implanted as a bridge-to-transplant ( $p<0.001$ ). We attribute these differences to  
288 technological evolution (recent CF-LVADs becoming available), better knowledge, and

289 better management capabilities, which help apply MCS to older patients and use LVADs  
290 as a destination therapy. Our registry shows lower in-hospital mortality (16.6% vs. 45.6%)  
291 than the previous report's entire and univentricular support cohorts ( $p < 0.001$ , central  
292 Figure), which we may explain by the exclusion of the more severe biventricular failure  
293 patients and the use of second- and third-generation CF-LVADs that better-perform first-  
294 generation CF-LVADs and pulsatile-flow LVADs.

295 In the GRAM registry the incidence of death at follow-up was lowest between three and  
296 six months after implantation, and tended to increase at later timepoints. Here we report a  
297 stable hazard rate between the sixth and the 24<sup>th</sup> post-operative months, irrespective of  
298 patients' age (Figure 3 Panel C). Remarkably, the UNOS database shows results similar to  
299 those of our registry [9]. We attribute the stable hazard rate to the better technology, the  
300 better post-operative medical management, and the standardized practices [7, 8].

301 We infer from these results that transplantation efficacy could improve if it was  
302 performed during the second post-implantation year, which may have major implications  
303 for the attribution of priority on list for heart transplantation. Moreover, as pre-implantation  
304 end-organ dysfunction is a known predictor of worse outcomes [10], we think that  
305 accelerating referral before organ failure or right ventricular dysfunction could improve  
306 patients' outcome.

307 Recent years have been characterized by expanding role of ECLS for the management of  
308 more severe cases of cardiogenic shock (INTERMACS class I-II). Although ECLS  
309 effectiveness is itself affected by baseline patient condition [11], it improves end-organ  
310 function and helps gain time for reflection in complex patients ('bridge-to-bridge' concept).  
311 Several studies show similar survival-rates under LVAD as those observed in  
312 INTERMACS class III-IV patients [12, 13, 14].

313

314 *Specificities in France of LVAD support and heart transplantation policy*

315 In 2004, to prioritize the attribution of cardiac grafts to patients under unweanable short-  
316 term mechanical circulatory assistance (ECLS) (degree 1) or to patients affected by  
317 complications under LVAD support (degree 2), France puts in place the national super-  
318 urgency system [15], which yielded fewer severe, ECLS-assisted patients undergoing  
319 long-term MCS, but also a better management of severe LVAD-related complications like  
320 pump pocket infections or pump thrombosis.

321 The proportion of transplanted patients in our registry is therefore remarkably lower than  
322 in the GRAM report (29.2% vs 47.9%). Our patients are also less likely to receive an  
323 LVAD as a bridge-to-transplant than in the previous GRAM report (87.9% vs 58.4%,  
324  $p < 0.01$ ) [3], which further contrasts with the EUROMACS cohort that only reports 28% of  
325 bridge-to-transplants [16]. Nevertheless, the INTERMACS database confirms the  
326 development of LVAD as a destination therapy since 50% of CF-LVADs implantation were  
327 for destination therapy in 2015, whereas bridge-to-transplantation and bridge-to-candidacy  
328 lowered to 26% and 23% more recently [17].

329 The historical one-year survival after heart transplantation is 75.2% in France [18], while  
330 for LVAD-recipients this survival was 78.6% between 2013 and 2015. In contrast, the  
331 ISHLT database reports an 84% one-year survival after heart transplantation between  
332 2006 and 2011, while considering a prior CF-LVAD implantation as an operative risk factor  
333 [19]. Additional reports suggest that previous cardiac surgery is linked with lower survival  
334 after transplantation [20]. Therefore, it matters to attentively select and prepare  
335 candidates, optimize follow-up under LVAD to limit complications, and to keep evaluating  
336 current CF-LVADs which are expected to provide better biocompatibility and quality of life.

337 Recent studies (second and third generation LVADs) fail to confirm the negative effect  
338 of previous LVAD therapy on survival after transplantation [21]. As a specific feature of the  
339 French national database, the best one-year survival after transplantation was observed  
340 among patients suffering from LVAD complication (80.1%) vs. patients transplanted for

341 other national priorities (75.5%), or without priority (75.1%). [18]. This needs to be  
342 considered by Heart Teams in the decision of timing of LVAD implantation in patients who  
343 deteriorate while on transplantation list.

344 At LVAD implantation, 29.2% of our patients were on temporary MCS (corresponding to  
345 INTERMACS classes I and II), whereas 53% were in cardiogenic shock. Although our  
346 register misses INTERMACS classification, these rates indicate a high proportion of high  
347 (I-II) INTERMACS profiles in our series. In the EUROMACS, the proportion of  
348 INTERMACS I patients was 12.1% in 2015 and 14% in 2017 [16, 22], therefore our  
349 registry would differ from the EUROMACS, which would explain some of the one-year  
350 survival difference between our registry (65.2%) and the EUROMACS (69%). Similarly, in  
351 the INTERMACS registry the rate of INTERMACS I patients ranges between 14 and 16%  
352 since 2008, and their one-year survival on CF-LVAD is 81%.

353 Major controlled trials over LVAD therapy tend to focus on less severe populations, e.g.,  
354 in the MOMENTUM 3 study [23] the rate of INTERMACS 1 profile was 0.8%. This feature  
355 is likely at the root of the markedly better survival in both MOMENTUM 3 cohorts [24] than  
356 in our registry. Also, this should be considered while comparing data with other published  
357 databases.

358 The current healthcare management policy in France includes extensive access of  
359 cardiogenic shock patients to ECLS as a bridge to recovery or bridge to decision. Along  
360 with dedicated hospital networks, France has 60 ECLS-implanting centers. Besides, E-  
361 CPR, i.e., ECLS for refractory cardiac arrest, is relatively diffuse. While indications for E-  
362 CPR were refined over time [25], E-CPR remains effective in selected cases, helping  
363 support the more challenging patients over the longer-term.

364 If we observe a significantly different survival under support by type of device (Figure 3  
365 Panel D), this difference may result from differences in baseline patient profiles, e.g.,  
366 different distribution of destination therapy strategy, which are more frequent among Jarvik

367 2000 vs. HeartMate II recipients. The distribution of complications and death causes also  
368 confirms the importance of neurological events as a drawback of LVAD therapy [7, 26, 27].  
369 To reduce the risk of pump thrombosis and stroke during initial follow-up, several new  
370 devices were proposed [28]. If those risks are indeed reduced, those results should be  
371 discussed along with the proposal to lower INTERMACS classes (3-4) of CF-LVAD  
372 therapy, i.e., destination therapy indications. However, to tackle the under-referral problem  
373 and better the patients' outcome, structured heart failure territorial networks and referral  
374 teams are also necessary. Optimal antithrombotic management under LVAD remains an  
375 open issue, too. If recent trials compare different antithrombotic strategies [29], such  
376 analysis is beyond the scope of this report.

377 At 30-days, center-volume analysis shows some heterogeneity (Figure 3 Panel A and  
378 Figure 4), but linear regression does not reveal any significant trend between center size  
379 and early survival ( $p=n.s.$ ). Nonetheless, in view of previous research suggesting that  
380 higher volume centers tend to perform better [6], we need to carry out additional analyzes  
381 to correctly interpret this aspect, e.g., by adjusting for the patients' baseline profile.

#### 382 Limitations.

383 Despite a large participation of French implanting centers, not all of them were actually  
384 involved, which we may explain by the different initial purposes of the current registry, i.e.,  
385 electrophysiology-related issues in LVAD recipients. Therefore, the ASSIST-ICD registry  
386 isn't fully representative of LVAD activity in France. Then, even though we used common  
387 data collection mechanisms, variable definitions, and a centralized analysis, our registry  
388 remains retrospective by design. We lack specific information like the INTERMACS class  
389 and the rate of temporary right heart MCS for severe right ventricular failure occurring later  
390 than arrival in the ICU. As well, we don't have statistics or reasons about LVAD-candidates  
391 who were denied LVAD at implanting centers.

#### 392 Conclusions.



393 The ASSIST-ICD registry provides a picture of recent (2007-2016) CF-LVAD activity in  
394 France. A real-life context is described, as all-comers inclusion criteria were adopted. As  
395 compared to previous historical periods, the main trends in France include increased  
396 average age of candidates, expanding use as a destination therapy, and better survival of  
397 the assisted patients. Evolving technology, better pre- and post-operative management,  
398 and the specific heart transplantation access policy in France lie among the reasons for  
399 such observation. The framework includes even access to long-term MCS, even for  
400 patients affected by advanced cardiogenic shock, a liberal use of ECLS (national  
401 healthcare strategy and reimbursement rules). We recommend earlier referral to LVAD.

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421

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424

425 **Conflict of Interest.**

426 None.

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**443 Figure Legends.**

444 **Figure 1. Panel A:** Yearly distribution of the number of implanted patients. **Panel B:**  
445 Yearly distribution of implanted devices.

446 **Figure 2.** Study flowchart.

447 **Figure 3.** Probability of the primary (alive under LVAD support or transplanted) or  
448 secondary endpoint (complication-free, alive under LVAD support, or transplanted) where  
449 bands characterize the 95% confidence interval, number of at risk patients, and hazard  
450 rate of the primary or secondary endpoint. The x-axis represents the time from surgical  
451 intervention. It follows a logarithmic scale. **Panel A:** Primary endpoint stratified per center  
452 size. **Panel B:** Primary endpoint stratified per gender. **Panel C:** Primary endpoint stratified  
453 per age at implantation, i.e., younger than 55, between 55 and 65; older than 65. **Panel D:**  
454 Primary endpoint stratified per type of LVAD. **Panel E:** Secondary endpoint stratified per  
455 type of LVAD.

456 **Figure 4.** Actual probability of 30-day survival according to center-size (funnel plot with  
457 95% and 99% confidence intervals)

**458 Central Image Legend.**

459 Between 2007 and 2016 in 20 out of 24 LVAD-implanting centers in France, probability of  
460 being alive under LVAD support or transplanted posterior to LVAD-implantation in the  
461 overall cohort (N=671).

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468 **Table 1.** Baseline (before LVAD implantation) characteristics of the registry population.

Characteristic	
Age (years)	57.7 (SD: 11.5)
Gender (male)	576 (85.8%)
BMI (kg/m <sup>2</sup> )	25.8 (SD: 4.7)
<u>Etiology of Cardiomyopathy</u>	
- Ischemic	418 (62.3%)
- Dilated idiopathic	187 (27.9%)
- Myocarditis	11 (1.6%)
- Cardiac valvopathy	9 (1.3%)
- Congenital cardiopathy	3 (0.4%)
- Other	43 (6.4%)
Heart failure duration (years)	8.4 (SD: 11.4)
ICD before LVAD	413 (31.5%)
CRT before LVAD	201 (29.9%)
History of supraventricular tachycardia	310 (46.2%)
LVEF (%)	20.5 (SD: 7.6)
LVEDD (mm)	69.5 (SD: 10.5)
LVEDV (mL)	247.5 (SD: 95.1)
PASP (mmHg)	50.3 (SD: 15)
TAPSE (mm)	16.2 (SD: 4.4)
Average tricuspid regurgitation degree (/4)	1.5 (SD: 1.0)
Right Atrial Pressure (mmHg)	10 (SD: 5.9)
PVR (Woods Units)	3.7 (SD: 7.3)
Serum creatinine (μmol/L)	129.8 (SD: 82.8)
Total bilirubin (mg/dL)	23.2 (SD: 78.2)
Hypertension	245 (36.5%)
Diabetes mellitus	164 (24.4%)
<u>Temporary circulatory support before LVAD</u>	
- Impella®	64 (9.5%)

- IABP	59 (8.8%)
- ECLS	144 (21.5%)
<u>Indication to LVAD therapy</u>	
- Bridge to Transplantation	392 (58.4%)
- Destination	260 (38.7%)
- Bridge to Recovery / Decision	6 (0.9%)
- Other	13 (1%)
<u>Associated procedure at LVAD implantation</u>	104 (15.5%)

469 *BMI: Body Mass Index. ICD: Implantable Cardioverter-Defibrillator. CRT: Cardiac*  
470 *Resynchronization Therapy. IABP: Intra-Aortic Balloon Pump. ECLS: Extracorporeal Life*  
471 *Support. LVEF: Left Ventricular Ejection Fraction. LVEDD: Left Ventricular End-Diastolic*  
472 *Diameter. LVEDV: Left Ventricular End-Diastolic Left Ventricular End-Diastolic Volume.*  
473 *PASP: Pulmonary Artery Systolic Pressure. TAPSE: Tricuspid Annular Plane Systolic*  
474 *Excursion. PVR: Pulmonary Vascular Resistance.*

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493 **Table 2.** Complications on LVAD support during the follow-up.

Characteristic	
<u>LVAD-related infection</u>	
- Driveline infection	175 (26.1%)
- Pump pocket / canula infection	85 (12.7%)
LVAD thrombosis	84 (12.5%)
LVAD replacement	35 (5.2%)
Ischemic stroke	86 (12.8%)
TIA	6 (0.9%)
Cerebral bleeding complications	37 (5.5%)
Noncerebral bleeding	86 (12.8%)

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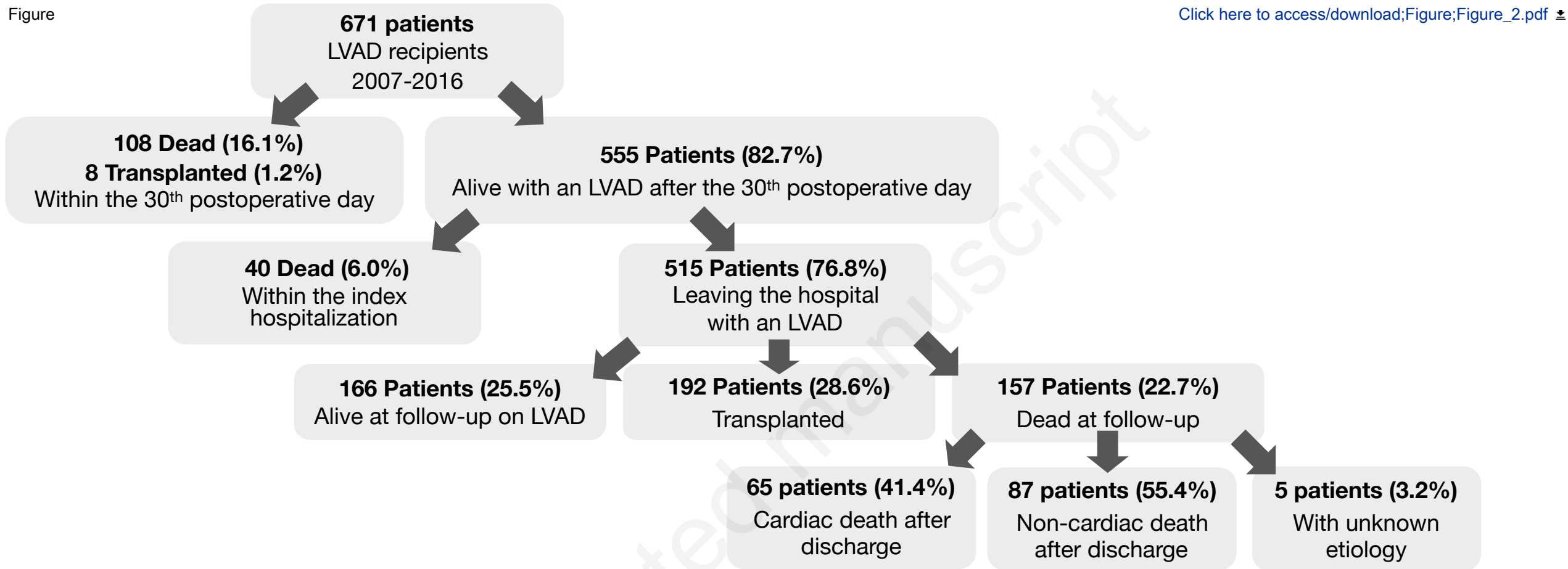
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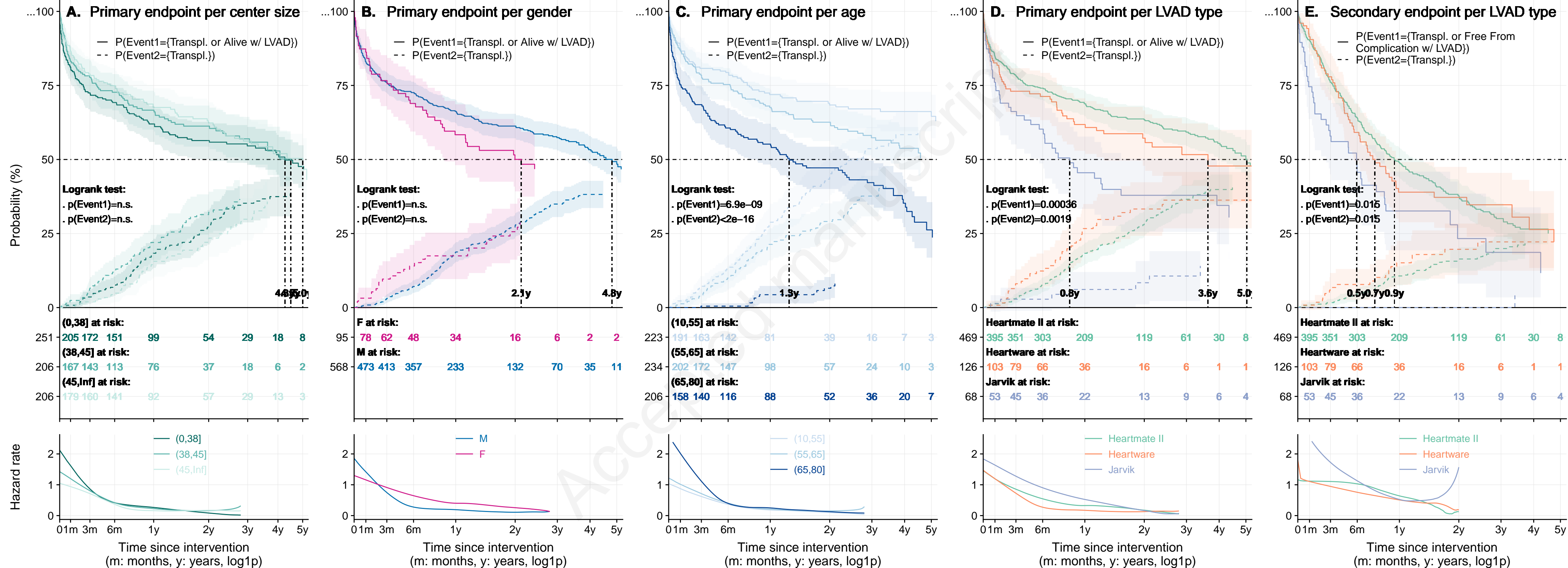
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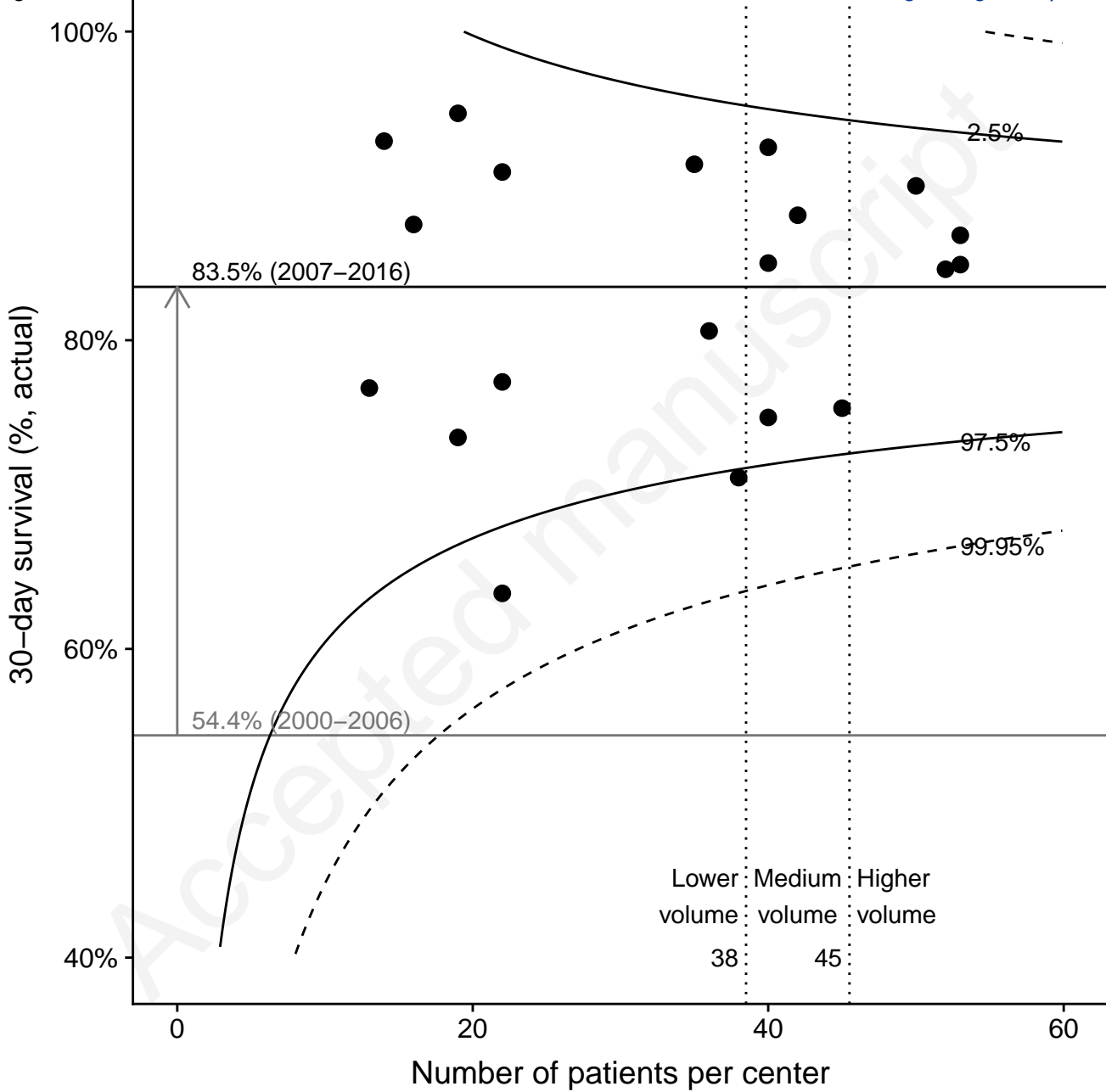


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