Longevity of implantable cardioverter-defibrillators for cardiac resynchronization therapy in current clinical practice: an analysis according to influencing factors, device generation, and manufacturer

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Received 16 February 2015; accepted after revision 28 March 2015; online publish-ahead-of-print 15 May 2015

Aims

Device replacement at the time of battery depletion of implantable cardioverter-defibrillators (ICDs) may carry a considerable risk of complications and engenders costs for healthcare systems. Therefore, ICD device longevity is extremely important both from a clinical and economic standpoint. Cardiac resynchronization therapy defibrillators (CRT-D) battery longevity is shorter than ICDs. We determined the rate of replacements for battery depletion and we identified possible determinants of early depletion in a series of patients who had undergone implantation of CRT-D devices.

Methods and results

We retrieved data on 1726 consecutive CRT-D systems implanted from January 2008 to March 2010 in nine centres. Five years after a successful CRT-D implantation procedure, 46% of devices were replaced due to battery depletion. The time to device replacement for battery depletion differed considerably among currently available CRT-D systems from different manufacturers, with rates of batteries still in service at 5 years ranging from 52 to 88% (log-rank test, \( P < 0.001 \)). Left ventricular lead output and unipolar pacing configuration were independent determinants of early depletion [hazard ratio (HR): 1.96; 95% confidence interval (CI): 1.57–2.46; \( P < 0.001 \); HR: 1.58, 95% CI: 1.25–2.01; \( P < 0.001 \), respectively]. The implantation of a recent-generation device (HR: 0.57; 95% CI: 0.45–0.72; \( P = 0.001 \)), the battery chemistry and the CRT-D manufacturer (HR: 0.64; 95% CI: 0.47–0.89; \( P = 0.008 \) ) were additional factors associated with replacement for battery depletion.

Conclusion

The device longevity at 5 years was 54%. High left ventricular lead output and unipolar pacing configuration were associated with early battery depletion, while recent-generation CRT-Ds displayed better longevity. Significant differences emerged among currently available CRT-D systems from different manufacturers.

Keywords

CRT • Implantable defibrillator • Longevity • Battery

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Introduction

Implantable cardioverter-defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-D) have been shown to be cost-effective therapeutic options, and have become standard treatment for the prevention of sudden cardiac death and the management of selected heart failure patients.

Patients who receive ICD and CRT-D devices must undergo device replacement at the time of battery depletion or in the case of other device-related or clinical events. Compared with ICDs, CRT-Ds are exposed to an increased risk of complications (lead dislodgment, infection, diaphragmatic stimulation, etc.), and are the most demanding antiarrhythmic devices in terms of battery consumption because of the need for continuous biventricular pacing and because pacing thresholds tend to be higher in the left ventricle.

Since device replacement is associated with a notable risk of complications and engenders costs for healthcare systems, device lifespan is a crucial determinant of the cost-effectiveness of therapy.

Projection on battery longevity provided by manufacturers is based on intensive laboratory testing under controlled conditions and might be different from device longevity in real life. Other information provided by the industry comes from product performance reports, and is based on the analysis of returned devices. However, cases of premature battery depletion may be underreported. Moreover, events such as infection, removal for system upgrade, heart transplantation, or patient death are not measured, and are estimated in analyses only by applying statistical adjustments and correction factors so as not to overstate the number of devices in service. Industry-independent analyses on longevity are scarce and have generally been performed on single-centre series that do not include currently available ICD models.

The aim of the present study was to measure the rate of replacements for battery depletion and to identify possible determinants of early depletion in a population of consecutive patients who had undergone implantation of CRT-D devices from different manufacturers.

Methods

Patient population and study design

Data on all patients who had received a CRT-D system according to international recommendations were prospectively collected in the hospital databases of nine Italian implanting centres. At the time of implantation, all patients signed a written informed consent for data storage and analysis.

In March 2014, data on all consecutive CRT-D systems implanted from January 2008 to March 2010 were retrieved for analysis, in order to estimate the proportion of devices in service more than 4 years after implantation.

All patients in the present analysis underwent implantation of a CRT-D, by means of standard techniques. After implantation, patients returned for regular clinic visits every 6 months and no remote monitoring system was adopted.

In all patients, the pacing output was programmed to ensure myocardial capture while avoiding phrenic nerve stimulation. Usually, voltage outputs were programmed to twice the threshold voltage assessed at pre-discharge and at periodical in-office visits. In all devices with algorithms for automatic threshold-capture determination and pacing output adjustment, the feature was programmed on.

Baseline data included the date of implantation, the manufacturer and model of the device and all leads implanted. Follow-up data included the pacing output and percentage pacing at the time of the last visit and the total number of shocks delivered.

In the present analysis, the study database was searched for all device-related events resulting in surgical intervention for device replacement. If pulse generator removal was required, the reason was verified and categorized as due to normal battery depletion or other causes.

The endpoint of this analysis was the rate of replacements for battery depletion. The service life of the device was defined as the time from implantation to surgical replacement.

Patients were censored at the time of death or the last outpatient follow-up visit. In the analysis of the time to battery depletion, removals for other causes were not counted as events and patients were censored at the time of their occurrence.

Statistical analysis

Descriptive statistics are reported as means ± SD for normally distributed continuous variables, or medians with 25th to 75th percentiles in the case of skewed distribution. Categorical variables are reported as percentages. Differences in proportions were compared by applying χ² analysis or Fisher’s exact test, as appropriate.

The pacing output was described in terms of pulse amplitude (<2.5 V, from 2.5 to 4 V, more than 4 V) and duration (<0.5 ms, from 0.5 to 1.0 ms, more than 1.0 ms). Biventricular pacing was quantified as: <90%, from 90 to 95%, or >95%. Similarly, the total number of delivered shocks was divided into groups (0, from 1 to 10, from 10 to 20, >20).

Kaplan–Meier analysis was used to analyse device longevity, and the log-rank test was applied to evaluate differences between trends (level of significance adjusted for multiple testing by Bonferroni correction). As differences in terms of service life were expected, the population was stratified by manufacturer and device generation. In the analysis of device generation, defibrillators from each manufacturer were divided into recent- and earlier-generation. We identified as recent-generation the most recent device families released onto the market (for the most part after 2007), and as earlier-generation all devices belonging to previous device families.

Hazard ratios (HRs) and their 95% confidence intervals (CIs) were computed by means of Cox regression models, in which device data were considered as fixed covariates and pulse generator replacements were considered as time-dependent covariates. After checking for collinearity, we included in the multivariate Cox models any variable with a P-value of <0.05 on univariate analysis. A P-value of <0.05 was considered significant for all tests. All statistical analyses were performed by means of STATISTICA software, version 7.1 (StatSoft, Inc., Tulsa, OK, USA).
Results

Study population
From January 2008 to March 2010, a total of 1726 heart failure patients received a CRT-D at the nine study centres. Details of the devices implanted are summarized in Table 1. The devices were from five manufacturers: 49 (3%) from Biotronik, 608 (35%) from Boston Scientific, 798 (46%) from Medtronic, 99 (6%) from Sorin, and 172 (10%) from St Jude Medical. They belonged to defibrillator families released onto the market from 2003 to 2010, and were equipped with different battery types. The devices of earlier-generation (released before 2007) and recent-generation families (released since 2007) were 708 and 1018, respectively.

The procedure was a de novo implantation in 1071 (62%) patients, a replacement of a previous CRT-D system in 472 (27%) patients, and an upgrade from a previous dual-chamber ICD in the remaining 183 (11%) patients. Two hundred and thirty-three (13%) patients were in atrial fibrillation and did not receive an atrial lead. A transvenous unipolar left ventricular lead was adopted in 385 (22%) systems, a transatrial bipolar lead in 1328 (77%) systems, and an epicardial unipolar lead in 13 (1%) systems. Unipolar leads were evenly distributed between the earlier-generation (155, 22%) and recent-generation groups (230, 23%). The right ventricular lead had an integrated bipolar design in 779 (45%) systems and a true-bipolar design in 13 (1%) systems. Unipolar leads were evenly distributed between the earlier-generation (155, 22%) and recent-generation groups (230, 23%). The right ventricular lead had an integrated bipolar design in 779 (45%) systems and a true-bipolar design in the remaining 947 (55%) systems. All devices were programmed to bipolar design in 779 (45%) systems and a true-bipolar design in the remaining 947 (55%) systems. All devices were programmed to deliver true biventricular pacing (right and left ventricular pacing).

Follow-up
During a median follow-up of 43 months (25th to 75th percentiles, 18–53; total follow-up, 5201 person-years), 479 (28%) devices were replaced/removed for any cause (Table 2). Specifically, 401 (23%) were replaced because of battery depletion, 40 CRT-Ds were removed because of device-related infection, and 7 devices were removed at the time of heart transplantation. Moreover, 31 pulse generators were replaced at the time of lead failure or elective replacement of a non-malfunctioning safety advisory lead.

During follow-up, 274 (16%) patients died before device replacement and 146 (8%) patients, evenly distributed among device manufacturers, did not complete the study period because they chose to continue follow-up in another device clinic and were therefore censored from the analysis.

The Kaplan–Meier estimate of time to device replacement for battery depletion in the overall study population is reported in Figure 1A. The actuarial probability of survival free from battery depletion was 81% at 4 years and 54% at 5 years.

The Kaplan–Meier estimates of time to device replacement for battery depletion, stratified by device manufacturer, demonstrated considerable differences in system longevity (overall log-rank test, \( P < 0.001 \); Figure 1B). Specifically, the actuarial rate of batteries still in service at 5 years ranged from 42% for Medtronic CRT-D to 66% for Boston Scientific generators.

The comparison of battery longevity between generations revealed significant improvements in recent devices from all manufacturers.

Table 1 Details (as reported in the device manuals) and numbers of devices in analysis

| Manufacturer                  | Device family | Year of market release (CE mark) | Battery type | Chemistry | Capacity | Devices in analysis |
|--------------------------------|---------------|----------------------------------|--------------|-----------|----------|---------------------|
| Biotronik, \( n = 49 \) (3%)  | Lumax 300     | 2006                             | Litronik     | GB 2491   | 1.28Ah   | 3                   |
|                               | Lumax 340     | 2006                             | Litronik     | GB 2491   | 1.28Ah   | 26                  |
|                               | Lumax 540*    | 2008                             | Litronik     | GB 2491   | 1.28Ah   | 20                  |
| Boston Scientific, \( n = 608 \) (35%) | Renewal      | 2004                             | Greatbatch   | 2000      | 2.00Ah   | 288                 |
|                               | Livian        | 2007                             | Greatbatch   | 2500      | 1.86Ah   | 29                  |
|                               | Cognis*       | 2008                             | Greatbatch   | 401988    | 1.84Ah   | 291                 |
| Medtronic, \( n = 798 \) (46%) | InSync III Marquis | 2003                        | Medtronic    | 161253    | 0.90Ah   | 67                  |
|                               | InSync Sentry | 2004                             | Medtronic    | 161253    | 0.89Ah   | 7                   |
|                               | InSync Maximo | 2005                             | Medtronic    | 161455    | 1.00Ah   | 171                 |
|                               | Concerto      | 2006                             | Medtronic    | 161455    | 1.00Ah   | 447                 |
|                               | Consulta*     | 2008                             | Medtronic    | 161455    | 1.00Ah   | 69                  |
|                               | Maximo II*    | 2008                             | Medtronic    | 161455    | 1.00Ah   | 16                  |
|                               | Protecta*     | 2010                             | Medtronic    | 161455    | 1.00Ah   |                      |
| Sorin, \( n = 99 \) (6%)      | Ovatio        | 2005                             | Greatbatch   | WGL 2393  | 0.87Ah   | 30                  |
|                               | Paradyne*     | 2008                             | Greatbatch   | GB 2593   | 1.96Ah   | b                   |
| St Jude Medical, \( n = 172 \) (10%) | Atlas        | 2003                             | Greatbatch   | 2255      | b        | 40                  |
|                               | Epic          | 2006                             | Greatbatch   | 2150      | b        | 26                  |
|                               | Promote*      | 2007                             | Greatbatch   | 2555      | b        | 106                 |

Li/MnO₂, lithium manganese dioxide; Li/SVO, lithium silver-vanadium oxide; Li/CFₓ-SVO, silver-vanadium oxide and carbon monofluoride.

*Considered as 'Recent-generation' for the purpose of the analysis.

bNot reported in the device manual.
manufacturers (log-rank test, \( P < 0.02 \) for all comparisons; Figure 2), except for Biotronik devices, ostensibly because of the small size of the subgroups in analysis.

Since longevity estimates may be imprecise when the sample is small, the comparison of longevity among recent-generation CRT-D from different manufacturers was performed only for subgroups with at least 100 devices in analysis; the results are reported in Figure 3. The rate of batteries still in service at 5 years was 52% for Medtronic, 75% for St Jude Medical, and 88% for Boston Scientific generators (log-rank test, \( P < 0.01 \) for pairwise comparisons).

Predictors of battery depletion

Table 3 shows data on pacing output and the percentage of biventricular pacing at the time of the last visit and the total number of shocks delivered. There were significant differences among manufacturers in terms of programmed pacing output. Specifically, the proportion of patients with left ventricular pulse amplitude <2.5 V and duration <0.5 ms was higher in the Medtronic group. Similarly, patients with Medtronic devices were less likely to receive a shock.

The device replacement procedure for battery depletion was independent of the percentage of biventricular pacing and the burden of defibrillator therapy (Table 4). However, it showed a significant association with the left ventricular lead output and with a unipolar pacing configuration. Moreover, the implantation of a recent-generation device, equipped with lithium manganese dioxide or hybrid silver-vanadium oxide, and carbon monofluoride batteries and a CRT-D from Boston Scientific were independent protective factors against early battery depletion. The multivariate analysis limited to recent-generation devices, confirmed following variables as independent factors associated with battery depletion: the left ventricular lead output (HR: 3.09, 95% CI: 2.18–4.38; \( P < 0.001 \)) and the Boston Scientific CRT-Ds (HR: 0.13, 95% CI: 0.04–0.40; \( P < 0.001 \)).

Discussion

Our analysis showed that 5 years after a successful CRT-D implantation procedure, 46% of devices were replaced on account of battery depletion, and left ventricular lead output and unipolar pacing configuration turned out to be independent determinants of early depletion. Recent-generation CRT-D (mostly released onto the market after 2007) displayed significantly greater longevity than those of early generations. Nonetheless, large differences in longevity seem to exist among currently available CRT-D systems from different manufacturers.

This study constitutes the largest multicentre analysis of consecutive patients who had undergone implantation of a recent CRT-D.
Landolina: longevity of CRT-D

Device longevity is based on battery technology, the efficiency of the electronic circuitry and the availability of specific algorithms for automatic pacing output adjustment, and varies not only among manufacturers but also among generations of devices from the same manufacturer. Indeed, on comparing the longevity of CRT-D belonging to different generations, we found significant improvements in recent devices. This result confirms previous findings by Schaefer et al.5 and Thijssen et al.6 In contrast, Horlbeck et al.8 did...
not observe better longevity in newer defibrillators. However, while in previous studies analysis by device generation was based on the time of implantation (i.e. before 2002 or since 2002), we stratified defibrillators according to the time of release onto the market (before or since 2007), in order to account for possible delays in the adoption of new technology in clinical practice.

Owing to these discrepancies in the performance of different CRT-D generations, comparison among manufacturers might be influenced by the mix of models in analysis. Nonetheless, our direct comparison of recent generations of CRT-D and the multivariate analysis limited to recent-generation devices confirmed the significantly longer lifespan of Boston Scientific defibrillators.

The recent-generation Boston Scientific defibrillators considered were equipped with high-capacity lithium manganese dioxide batteries, which resulted in a markedly longer lifespan than that of previous generations. In contrast, the Medtronic and St Jude Medical CRT-Ds released onto the market after 2007 and included in the present analysis were equipped with the same lithium silver-vanadium oxide battery used in early generations. However, although the chemistry was the same, St Jude Medical adopted different battery models for its recent CRT-Ds. This, together with a possible improved efficiency of the electronic circuitry, may explain the improved performance of its recent-generation devices.

The majority of the recent Medtronic CRT-Ds was endowed with algorithms for automatic pacing output adjustment, which have been demonstrated to reduce pacing output in comparison with the standard manual management approach. This may have determined the observed improvement in longevity.

The importance of pacing output optimization is supported by the significant positive association that we noticed between left ventricular lead output and early depletion, confirming previous findings by Thijssen et al. and Alam et al. This can easily be explained by

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**Table 3** Pacing output, percentage of biventricular pacing, and total number of shocks delivered, by device manufacturer

|                          | Biotronik | Boston Scientific | Medtronic | Sorin | St Jude Medical |
|--------------------------|-----------|-------------------|-----------|-------|----------------|
| Patients with high right atrial lead output (%) | 0         | 5                 | 6         | 4     | 1              |
| Patients with high right ventricular lead output (%) | 2         | 5                 | 4         | 1     | 5              |
| Patients with high left ventricular lead output (%) | 13        | 31                | 18        | 31    | 26             |
| % of patients with biventricular pacing: <90%/90–95%/≥95% | 10/13/77  | 12/10/77          | 9/14/76   | 16/18/65 | 11/13/75       |
| % of patients with shocks delivered: 0/1–10/10–20/>20 | 64/36/0/0* | 69/29/1/1*        | 85/13/0/1 | 83/17/0/0 | 74/26/0/0*     |

High pacing output: pulse amplitude >2.5 V and duration >0.5 ms.

*P < 0.05 vs. Medtronic.

**Table 4** Univariate and multivariate analysis of factors associated with replacement for battery depletion in the overall population

|                          | Univariable analysis | Multivariable analysis |
|--------------------------|----------------------|------------------------|
|                          | HR 95% CI            | P-Value                | HR 95% CI            | P-Value                |
| Biotronik                | 0.75 0.40–1.41       | 0.369                  | –                      | –                      |
| Boston Scientific        | 0.54 0.43–0.67       | <0.001                 | 0.64 0.47–0.89        | 0.008                  |
| Medtronic                | 1.00 –               | –                      | 1.00 –                | –                      |
| Sorin                    | 0.83 0.53–1.30       | 0.415                  | –                      | –                      |
| St Jude Medical          | 0.74 0.52–1.05       | 0.089                  | –                      | –                      |
| Recent generation        | 0.50 0.40–0.61       | <0.001                 | 0.57 0.45–0.72        | <0.001                 |
| Battery chemistry: Li/SVO| 1.00 –               | –                      | 1.00 –                | –                      |
| Battery chemistry: Li/CFx-SVO | 0.42 0.24–0.72 | 0.002                 | 0.28 0.16–0.50        | <0.001                 |
| Battery chemistry: Li/MnO2 | 0.20 0.13–0.33      | <0.001                 | 0.37 0.22–0.64        | <0.001                 |
| High right atrial lead outputa | 0.70 0.39–1.24 | 0.219                  | –                      | –                      |
| High right ventricular lead outputa | 1.38 0.83–2.31 | 0.217                  | –                      | –                      |
| High left ventricular lead outputa | 1.74 1.39–2.18 | <0.001                 | 1.96 1.57–2.46        | <0.001                 |
| Unipolar left ventricular lead | 1.71 1.37–2.13 | <0.001                 | 1.58 1.25–2.01        | <0.001                 |
| True-bipolar right ventricular lead | 1.47 1.21–1.79 | <0.001                 | 1.00 0.78–1.30        | 0.978                  |
| Percentage of biventricular pacing | 1.20 0.91–1.58 | 0.207                  | –                      | –                      |
| Shocks delivered         | 1.58 0.59–4.20       | 0.365                  | –                      | –                      |

LiMnO2, lithium manganese dioxide; Li/SVO, lithium silver-vanadium oxide; Li/CFx-SVO, silver-vanadium oxide and carbon monofluoride.

aPulse amplitude >2.5 V and duration >0.5 ms.
the considerable battery drainage caused by the high pulse amplitude and duration required for consistent capture of the left ventricle, and by the need for continuous biventricular pacing. Moreover, the higher battery drainage with unipolar left ventricular pacing configurations can be ascribed to the lower pacing impedance and thus to the higher current consumption.18 As previously reported by Alam et al.,9 despite longer service life, Boston Scientific CRT-Ds had higher programmed pacing output, most probably owing to the absence of algorithms for automatic pacing output adjustment. Moreover, Boston Scientific CRT-Ds were most likely to deliver a shock, ostensibly because of the longer lifespan of each device and thus the longer exposure to the risk of arrhythmias. Nonetheless, our results suggest that battery depletion was independent of the burden of defibrillator therapy, confirming previous findings.5–7,9 A more relevant factor might be the capacitor reformation interval,6 but we did not include this parameter in our model.

In addition, the percentage of biventricular pacing was not responsible for the observed longevity differences in CRT-D devices. This finding, specifically attributable to the fact that the percentage of pacing with CRT-D is generally close to 100%, might not apply to single- and dual-chamber defibrillators, which display higher variability in pacing burden.6–8

**Limitations**

Some limitations of this study should be noted. First, the baseline clinical characteristics of the patients were not analysed. However, the results should have not been affected by any bias, as previous studies had failed to show any association between clinical characteristics and defibrillator lifespans.6–8 Secondly, it should be mentioned that not all pacing parameters were included in analysis (e.g. rate response) and data on pacing output and the percentage of biventricular pacing were only gathered at the last interrogation of the device and not throughout the entire period of its functioning. However, we assumed that these values could represent reliable surrogates of measurements over the lifespan of the device. Thirdly, although the rates of events were statistically different among the manufacturers, the proportion of replacements among devices displaying a longer lifespan was low. Thus, longer follow-up periods are warranted in order to estimate the actual lifespan of these devices. Fourthly, in this study no information was available regarding the time from device production to implantation. Nonetheless, longer follow-up periods are warranted in order to estimate the actual lifespan of these devices. Moreover, in this study no information was available regarding the time from device production to implantation. Nonetheless, longer follow-up periods are warranted in order to estimate the actual lifespan of these devices.

**Conclusions**

In a large population of consecutive patients with CRT-D, the device longevity at 5 years was 54%. Recent-generation CRT-Ds displayed better longevity than those of earlier generations. Moreover, differences emerged among currently available CRT-D systems from different manufacturers, with rates of batteries still in service at 5 years ranging from 52 to 88%. According to our results the next step, already undertaken by manufacturers, towards the goal of providing a lifetime CRT-D system should be a device with latest-generation high-capacity batteries and with algorithms for the optimization of left ventricular pacing.

**Funding**

Funding to pay the Open Access publication charges for this article was provided by Boston Scientific Italia.

**Conflict of interest:** This was an independent study. No external funding was achieved for this project. M.L. has a speakers’ bureau appointment with St Jude Medical, Medtronic, and Boston Scientific and an advisory board relationship with St Jude Medical and Medtronic. M.G. has an advisory board relationship with Boston Scientific. The other authors report no conflicts.

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Atrioventricular node ablation: patient monitoring and pacing rate adjustment might be needed

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A 60-year-old male patient, treated for mild arterial hypertension, was referred for highly symptomatic long-standing persistent atrial fibrillation (CHA2DS2VASc = 1) after a previously failed radiofrequency biatrial catheter ablation. A fast ventricular response was present despite β-blocker therapy (the mean heart rate of 130 b.p.m. on 24-h Holter), and the patient developed tachycardia-induced cardiomyopathy (left ventricular (LV) ejection fraction 45% with NYHA III). A biventricular pacemaker was implanted, and atrioventricular node ablation was performed the day after. The pacing rate was programmed at 90 b.p.m. (Paced QT interval measured at 460 ms). Two hours after ablation, the patient developed frequent premature ventricular contractions with bigeminy (coupling interval 400 ms), and finally ventricular fibrillation (VF) (Panel A) requiring urgent external cardioversion. Coronary angiogram performed after the episode was normal. The pacing rate was then increased to 110 b.p.m. during 1 week with β-blocker continuation (Panel B). The pacing rate at discharge was finally set at 100 b.p.m. for the first month. No ventricular arrhythmia was observed after 1-year follow-up, and LV function completely recovered.

We think that a particularly high mean rate pre-ablation may favour VF occurrence despite standard pacing rate programming at 90 b.p.m. The later may be prevented by further increase in the post-ablation pacing rate.

The full-length version of this report can be viewed at: http://www.escardio.org/communities/EHRA/publications/ep-case-reports/Documents/Atrioventricular_node_ablation.pdf.

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