#### ORIGINAL ARTICLES

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# Multi-lead cephalic venous access and long-term performance of high-voltage leads

Zaki Akhtar MBBS<sup>1,2</sup> | Idris Harding MBBS<sup>1</sup> | Ahmed I. Elbatran MBBS, MSc<sup>1,3</sup> Hanney Gonna MBBS<sup>1</sup> | Nilanka N. Mannakkara MBBS<sup>1</sup> | Lisa W. M. Leung MBChB<sup>1</sup> | Zia Zuberi PhD<sup>1,4</sup> | Abhay Bajpai MD<sup>1,5</sup> | Simon Pearse MD<sup>1,6</sup> | Andrew T. Cox MB<sup>1,7</sup> | Anthony Li MD<sup>1</sup> | Fadi Jouhra MD<sup>1</sup> | Oswaldo Valencia MD<sup>1</sup> | Zhong Chen PhD<sup>2</sup> | Manav Sohal MD<sup>1</sup> | Ian Beeton MD<sup>2</sup> | Mark M. Gallagher MD<sup>1,2,5</sup>

<sup>1</sup>Department of Cardiology, St George's University Hospital, London, UK

<sup>2</sup>Department of Cardiology, Ashford and St Peter's Hospitals NHS Trust, Surrey, UK

<sup>3</sup>Department of Cardiology, Ains Sham University, Cairo, Egypt

<sup>4</sup>Department of Cardiology, Royal Surrey County Hospital, Guildford, Surrey, UK

<sup>5</sup>Department of Cardiology, Epsom and St Helier NHS Trust, Surrey, UK

<sup>6</sup>Department of Cardiology, Kingston Hospital NHS Trust, London, UK

<sup>7</sup>Department of Cardiology, Frimley Park NHS Foundation Trust, UK

#### Correspondence

Mark M. Gallagher, MD, St George's University Hospital, Blackshaw Roadm, London SW17 0QT, UK. Email: Mark\_M\_Gallagher@hotmail.com

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#### Abstract

**Background:** Cardiac resynchronization therapy-defibrillator (CRT-D) implantation via the cephalic vein is feasible and safe. Recent evidence has suggested a higher implantable cardioverter-defibrillator (ICD) lead failure in multi-lead defibrillator therapy via the cephalic route. We evaluated the relationship between CRT-D implantation via the cephalic and ICD lead failure.

**Methods:** Data was collected from three CRT-D implanting centers between October 2008 and September 2017. In total 633 patients were included. Patient and lead characteristics with ICD lead failure were recorded. Comparison of "cephalic" (ICD lead via cephalic) versus "non-cephalic" (ICD lead via non-cephalic route) cohorts was performed. Kaplan-Meier survival and a Cox-regression analysis were applied to assess variables associated with lead failure.

**Results:** The cephalic and non-cephalic cohorts were equally male (81.9% vs. 78%; p = .26), similar in age (69.7 ± 11.5 vs. 68.7 ± 11.9; p = .33) and body mass index (BMI) (27.7 ± 5.1 vs. 27.1 ± 5.7; p = .33). Most ICD leads were implanted via the cephalic vein (73.5%) and patients had a mean of 2.9 ± 0.28 leads implanted via this route. The rate of ICD lead failure was low and statistically similar between both groups (0.36%/year vs. 0.13%/year; p = .12). Female gender was more common in the lead failure cohort than non-failure (55.6% vs. 17.9%, respectively; p = .004) as was hypertension (88.9% vs. 54.2%, respectively, p = .038). On multivariate Coxregression, female sex (p = .008; HR, 7.12 [1.7–30.2]), and BMI (p = .047; HR, 1.12 [1.001–1.24]) were significantly associated with ICD lead failure.

Abbreviations: AF, atrial fibrillation; COPD, chronic obstructive pulmonary disease; DCM, dilated cardiomyopathy; DM, diabetes mellitus; F, female; HTN, hypertension; IBD, inflammatory bowel disease; ICD, implantable cardioverter defibrillator; IHD, ischemic heart disease; M, male.

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**Conclusion:** CRT-D implantation via the cephalic route is not significantly associated with premature ICD lead failure. Female gender and BMI are predictors of lead failure.

KEYWORDS

cephalic, CRT-D, implantable cardioverter defibrillator, lead failure, venous access

# 1 | INTRODUCTION

The cardiac resynchronization therapy-defibrillator (CRT-D) is an established treatment for heart failure which reduces morbidity and mortality.<sup>1</sup> The pacing leads are predominantly implanted via the transvenous approach, usually by subclavian or axillary puncture and sometimes by cephalic vein cut-down. There is no standard approach, but cephalic access is feasible, effective, and safe<sup>2,3</sup> irrespective of the number of leads being implanted.<sup>4</sup> Traditional lateral subclavian vein puncture has been associated with a higher rate of lead failure than the use of cephalic venous access<sup>5,6</sup> but a recent report has suggested that multi-lead defibrillator therapy utilizing the cephalic route is associated with early implantable cardioverter-defibrillator (ICD) lead failure.<sup>7</sup>

# 2 | METHODS

Data were collected retrospectively for patients with a CRT-D implant between October 2008 and September 2017 from three centers. The follow-up duration was determined from implantation to either lead failure, patient death, or end of the study

period. The implantation technique varied among the 12 operators. A minority of operators used venogram-guided lateral axillary (or subclavian) access as the method of the first choice. Cephalic cut-down was preferred by most operators and has been reported previously.<sup>2,4</sup> Following isolation of the cephalic vein with blunt dissection close to the level of the coracoid process, the distal end of the vein was tied and a precise transverse venotomy was performed at this anatomical level. Two standard 50 cm 0.97 mm guidewires and a 150 cm angled 0.97 mm hydrophilic guidewire (Radiofocus RF\*GA35153M, Terumo Corporation) were introduced and advanced towards the heart. Initially, the coronary sinus (CS) delivery system was advanced over the hydrophilic guidewire, to position the CS lead (with contrast venogram) in a suitable cardiac vein. Peel-away sheaths were then used to position an atrial lead (7 fr sheath) and an ICD ventricular lead (9 fr sheath). When this vessel was too small to allow access to all the leads, either the axillary or subclavian was used for the remainder. It was at the operator's discretion to decide which lead to place by other routes of access.

Pacing interrogation was performed within 24 h after implantation, at 6 weeks, and subsequently at 6-month intervals. Patients



**FIGURE 1** Bar graph demonstrating the distribution of implant routes for other leads according to the implantation route of the high-voltage lead (A, B) and the distribution of access route for high voltage leads according to lead model (C). All systems included a left ventricular lead; 91% included an atrial lead. (A) When the high-voltage lead was implanted via the cephalic vein, the other leads followed the same route in 98.7% of cases. (B) When the ICD lead was non-cephalic, 78.6% of the other leads were also non-cephalic. (C) The Sprint Quattro (Medtronic) and the Endotak Reliance (Boston Scientific) leads were used in the majority of our population with a similar distribution of cephalic and non-cephalic access used across all lead models. ICD, implantable cardioverter-defibrillator

with defibrillator leads implanted via the cephalic vein were categorized as the "cephalic" group and patients in whom the defibrillator lead was implanted utilizing the subclavian or axillary veins, were categorized as the "non-cephalic" group.

# 2.1 | Lead failure

Lead failure was defined as per the Heart Rhythm Society consensus.<sup>8</sup> High-voltage leads were considered to have failed if they exhibited: persistent oversensing of non-physiological rapid signals, the abnormal impedance in the pace/sense or the shock component, an increase in right-ventricular lead threshold, and/or decrease in sensing sufficient to make the lead unreliable.<sup>8</sup> All leads that met these criteria were extracted and replaced; all were inspected carefully before and after extraction. Lead extraction for infection and lead revision for displacement were considered separately. Radiological images from the time of implantation were inspected for all leads that subsequently failed.

# 2.2 | Statistical analysis

Continuous variables were conveyed as a mean ± standard deviation and median with interquartile range (IQR), whilst categorical variables were presented as a number and percentage. Statistical analysis was performed using a  $\chi^2$  test and an independent *t* test. A *p* < .05 was considered significant. Lead longevity was analyzed using the Kaplan–Meier model and risk factors were compared using a univariate, multi-variate, and Cox regression analysis.

# 3 | RESULTS

Over the study period, 633 patients underwent CRT-D therapy and were included in the analysis. In most cases (73.5%), the high-voltage lead was implanted via the cephalic vein (cephalic group) while the remainder were axillary (21.9%) and subclavian (4.6%) access; the majority (50.3%) of the implanted ICD leads were Sprint Quattro (Medtronic) (Figure 1). Both groups were predominantly male (81.9% vs. 78%, respectively; p = .26) of a similar age (69.7 ± 11.5 years vs. 68.7 ± 11.9, respectively; p = .33) and had a left-sided implant (96.6% vs. 97%; p = .72) for primary prevention (91.2% vs. 92.9%; p = .5). Co-morbidities in both groups were fairly similar (Table 1) although chronic kidney disease was more prevalent in the cephalic group (16.3% vs. 10.1%, respectively; p = .05). The mean follow-up period was 4.75 ± 2.4 years. The overall lead failure rate in this study was 0.3%/year.

During the study period, 20 patients required revision or replacement of the RV lead. Of these, six (30%) patients had an infection indication, including erosion, local infection, and systemic sepsis. Early lead replacement for displacement or cardiac perforation accounted for 4 (20%) cases and the remaining 10 (50%) were premature lead failures.

High-voltage lead failure was rare; failure occurred at a nonsignificant higher rate of 0.36% per year in the cephalic group (8 of

#### **TABLE 1** A comparison of the cephalic and non-cephalic groups

	ICD lead "cephalic"	ICD lead "non-cephalic"	p value
Ν	465 (73.5%)	168 (26.5%)	<.001
Male	381 (81.9%)	131 (78%)	.26
Age	69.7 ± 11.5	68.7 ± 11.9	.33
Number of leads	$2.91 \pm 0.35$	2.88 ± 0.32	.4
BMI	27.7 ± 5.1	27.1 ± 5.7	.33
lschemic cardiomyopathy	347 (74.6%)	125 (74.4%)	.96
IHD	339 (72.9%)	120 (71.4%)	.72
Diabetes	118 (25.4%)	49 (29.2%)	.34
CKD	76 (16.3%)	17 (10.1%)	.05
Hypertension	257 (55.3%)	89 (53%)	.61
Atrial fibrillation	168 (36.1%)	54 (32.1%)	.35
LVEF (%)	$28.4 \pm 8.2$	28.4 ± 8.6	.96
Procedure (min)	120.6 ± 46.6	143.9 ± 44.8	<.001
RV lead failure	8 (1.72%)	1 (0.6%)	.29
Lead follow-up (months) to failure, death, or study end	58.7 ± 30.1	52.2 ± 24.6	.006
Left sided implant	449 (96.6%)	163 (97%)	.72
Primary prevention	424 (91.2%)	156 (92.9%)	.5
Single coil	217 (46.7%)	99 (58.9%)	<.01
Dual coil	248 (53.3%)	69 (41.1%)	<.01
Sprint Quattro	234 (50.3%)	79 (47%)	.9
Endotak reliance	159 (34.2%)	59 (35.1%)	.9
Linox	32 (6.9%)	13 (7.7%)	.9
Other leads	40 (8.6%)	17 (10.1%)	.9

*Note*: On average a statistically significantly higher number of leads were implanted via the cephalic, than non-cephalic routes. The procedure was also noted to be longer in the non-cephalic procedures. However, there was no significant difference in the number of ICD lead failures between the two groups (p = .29).

Abbreviations: BMI, body mass index; CDK, chronic kidney disease; ICD, implantable cardioverter defibrillator; IHD, ischemic heart disease; LVEF, left ventricular ejection fraction.

462 implants), in comparison to the 0.13% per year in the noncephalic group (1 of 171 implants) (p = .12; Figure 2). There was no significant difference in the failure rate of individual lead models (Sprint Quattro, Endotak Reliance, Linox; 0.27%/year, 0.2%/year, 0.41%/year, respectively; p = .82) (Figure 3). The number of shock coils, the number of concomitant leads implanted with the defibrillator lead and the ICD lead tip position within the right ventricle, did not affect lead longevity (Figure 2). However, ICD leads implanted in female patients for CRT-D, were more likely to experience premature failure (p = .018) (Figure 4).



**FIGURE 2** Kaplan-Meier curves describing lead survival. (A) No significant difference in survival of ICD leads was detected between those implanted via the cephalic and non-cephalic routes. (B) ICD lead implanted in septal and apical locations lasted equally well. (C) Durability of the ICD lead was not influenced by the number of leads implanted via the cephalic vein. (D) The number of coils of the implanted ICD lead does not affect lead longevity. ICD, implantable cardioverter-defibrillator

# 3.1 | Comparison of lead failure and non-failure cohorts

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Comparison of the ICD lead failure and non-failure cohorts was performed for baseline patient characteristics (Table 2). There was a significantly higher proportion of female (55.6% vs. 17.9%; p = .004) and hypertensive patients (88.9% vs. 54.2%; p = .038) in the lead failure group. There was a trend toward patients of higher body mass index (BMI) (31.7 vs. 27.4; p = .17) and toward a longer implantation procedure duration (137.4 vs. 126.5 min; p = .7) in the lead failure group. A similar proportion of ICD leads were implanted via the cephalic in lead failure and non-failed groups (88.9% vs. 73.2%; p = .24). When the ICD lead was implanted via the cephalic vein, a statistically similar number of leads were implanted via this route concomitantly, in both cohorts (2.56 vs. 2.83, lead failure vs. non-failure, respectively; p = .43).

# 3.2 | Predictors of lead failure

A univariate logistic regression analysis of the whole study population was performed for predictors of lead failure (Supporting Information). Female gender (p = .012; OR, 5.52 [1.46–20.9]) and BMI (p = .03; OR, 1.12 [1.01–1.25]) were significant factors, whilst hypertension was correlated although it did not reach statistical significance (p = .072; OR, 6.8 [0.84–54.4]). When entered in to a Coxregression analysis, female gender (p = .008; HR, 7.12 [1.7–30.2]) and BMI (p = .047; HR, 1.12 [1.001–1.24]) were significant predictors of lead failure (Table 3). Hypertension although correlated, did not reach statistical significance as a predictor of lead failure (p = .051; HR, 8.74 [0.99–77.4]).

# 4 | DISCUSSION

The current series is the largest to date evaluating the relationship between multi-lead defibrillator therapy delivered via the cephalic vein, and ICD lead failure. We found a very low incidence of lead failure in this solely CRT-D based study (0.3%/year). The findings have important practical applications as CRT-D system implantations via the cephalic are efficient and safe,<sup>4</sup> while ICD lead failures maintain a degree of concern.<sup>7</sup>



**FIGURE 3** Kaplan-Meier survival curves of lead models. There was no significant difference in lead longevity of the three most frequently used leads at our institutes (A). The mode of venous access had no statistically significant effect on the survival of the Sprint Quattro (B), Endotak Reliance (C) or Linox (D) high-voltage leads

This multi-center study reported a very low overall lead failure rate which is at odds with some previous series<sup>7</sup> but is validated by a previous large series (0.45%/year).<sup>9</sup> This low failure rate may reflect our conservative practice: a policy of



**FIGURE 4** Kaplan-Meier curve of ICD lead survival by gender. The rate of defibrillator lead survival was significantly poorer in female patients, compared to their male counterparts (p = .018). ICD, implantable cardioverter-defibrillator

concentrating on products with a track record of long-term safety and late adoption of less tested technology. The higher incidence of failure in the prior literature may represent a publication bias; it is reasonable to suppose that colleagues are more likely to report an unsatisfactory experience than to describe a lead performance that is in line with expectation.

series demonstrates that cephalic vein access This for multi-lead defibrillator therapy does not affect ICD lead longevity: the rate of lead failure was similarly low for cephalic and non-cephalic routes (0.36%/year vs. 0.13%/year; p = .12). This is in stark contrast to a recent report by Barbhaiya et al.<sup>7</sup> which found that cephalic access was significantly associated with a high rate of lead failure in multi-lead ICD therapy (11% per year for non-Linox and 19% per year for Linox leads). There are significant differences between the two reports. Their method was to implant a maximum of two leads via the cephalic vein, whereas most of our patients received three leads by this route. Barbhaiya et al described only 46% of their cohort as having multi-lead ICD systems, our study population consists entirely of CRT-D devices (≥ 2 leads). They implanted only 18% of ICD leads via the cephalic vein, while we used it in 73.5%. This implies that their series included only around 55 ICD leads implanted via the cephalic as part of a multi-lead system compared to 465 in our series.

Our data include a trend toward a higher rate of ICD lead failures in the cephalic group but it is well within the margin of error; failure patients

	Lead failure	Lead non-failure	p value
Ν	9	624	
Age	64 ± 9.7	69.5 ± 11.6	.13
Female	55.6%	17.9%	.004
Implantation procedure duration (min)	137.4 ± 82.1	126.5 ± 46.6	.7
Ischemic heart disease	66.7%	72.6%	.69
Diabetes	22.2%	26.4%	.78
Chronic kidney disease	0	14.9%	.21
Hypertension	88.9%	54.2%	.038
Atrial fibrillation	22.2%	35.3%	.41
Body mass index	31.7 ± 8	27.4 ± 5.2	.17
Left ventricular ejection fraction (%)	26.1 ± 5.7	28.4 ± 8.3	.33
Lead age to failure or end of follow-up (months)	49.6 ± 31.1	57.1 ± 28.9	.49
Cephalic access (%)	88.9%	73.2%	.24
Number of cephalic leads when ICD lead cephalic	2.56 ± 1	2.83±0.4	.43

Abbreviation: ICD, implantable cardioverter defibrillator.

 TABLE 3
 Cox-regression analysis for variates of lead failure

Variable	Hazard ratio	95% CI	p value
Female gender	7.124	1.68-30.208	.008
Hypertension	8.744	0.988-77.418	.051
Body mass index	1.116	1.001-1.243	.047
ICD lead cephalic access	2.056	0.247-17.144	.505

Abbreviations: CI, confidence interval; ICD, implantable cardioverterdefibrillator.

the use of non-cephalic access is too unusual in our series to permit us to analyze the difference. The sample size for cephalic implants is far larger and is sufficient to demonstrate clearly that the high failure rate of high voltage leads implanted via cephalic access as part of multi-lead systems reported by Barbhaiya et al is not reproduced in the center contributing to our series.

Sample size alone cannot account for the contrast between our results and those of Barbhaiya et al. As their series included just six instances of lead failure including four (67%) implanted via the cephalic route, the association may have been a chance event detected on post-hoc analysis. Inter-institution differences in implantation technique could also have played a role: Barbhaiya et al.<sup>10</sup> demonstrated that the phenomenon they described was not attributable to a single operator, but institutional culture determines the idiosyncrasies of operative technique as much as interindividual variation. All of the predominantly cephalic operators in our series derived at least part of their methodology from one mentor.

We believe that many small technical<sup>11</sup> and methodological differences could play a role in lead durability: for example, our policy is to place all leads via peel-away sheaths to protect the tip from stress produced by passage through a tortuous cephalic vein. In our series, 75% of the operators would be considered as "cephalic-operators" with a similar well-honed technique and experience in accessing this vein, maintaining consistency, and minimizing error. It can be argued this may skew the findings, but it represents a multi-institutional experience that is consistent and reproducible with favorable outcomes.

Our population included a low proportion of leads that are associated with a high rate of failure (Table 4). The Sprint Fidelis (Medtronic) had been withdrawn before the study recruitment period; the Riata was seldom used in our centers. The Linox (Biotronik) which has been associated with an elevated failure rate in some series<sup>12,13</sup> but not all<sup>7,14</sup> demonstrated similar performance to other models, but the comparison is underpowered.

The Cox regression analysis found that the venous access route does not predict lead failure (p = .5), in keeping with prior reports.<sup>15</sup> Consistent with previous findings, we found leads implanted in women were much more likely to fail<sup>16</sup> (Figure 4). The naturally smaller female frame may enforce tighter angulation within the thoracic vasculature, applying stress on the implanted leads. Due to their smaller size, women are also more likely to have excess redundant lead folded within the pocket, increasing lead tension at this site.

There was an obvious trend indicating an association between hypertension and premature lead failure in our series but due to a small number of lead failure events, it did not reach statistical significance (p = .051). It stands to reason as a hazard to lead durability: Hypertension results in shear stress on the vascular system leading to remodeling with increased tortuosity and angulations in the arterial system. The venous system is not directly altered by arterial hypertension, but the close anatomic relationship could expose venous leads indirectly to stress arising from the angulations of the associated arteries (Figure 5).

#### 4.1 | Limitations

This study was a retrospective analysis and therefore open to bias from confounding variables. Remote monitoring was available only for a minority of devices across the study period and may result in

Patient	Prevention	Gender	Age	Co-morbidities	BMI	Number of leads via the cephalic	ICD lead access	LVEF (%)	ICD lead	Coils	Implant procedure duration (min)	Time to lead failure (years)
1	Secondary	Σ	70	IHD, HTN, IBD	22	7	Cephalic	25	Sprint Quattro 6947	Dual	309	0.1
0	Secondary	ш	52	IHD, DM, RA, Asthma, HTN	35	ę	Cephalic	20	Linox SD65	Dual	81	5.8
e	Secondary	ш	63	DCM, HTN	36	ю	Cephalic	25	Sprint Quattro 6935	Single	122	4.4
4	Primary	ш	71	IHD, HTN, COPD	29	ю	Cephalic	30	Sprint Quattro 6935	Single	172	0.1
5	Primary	ш	46	IHD, IBD	48	e	Cephalic	25	Endotak Reliance 0181	Single	54	5.0
9	Primary	Σ	75	DCM, HTN, AF	30	e	Cephalic	35	Endotak Reliance 0181	Single	85	3.3
7	Primary	Σ	73	DCM, HTN	27	т	Cephalic	20	Sprint Quattro 6947	Dual	69	4.6
00	Primary	ш	64	IHD, HTN,	26	0	Axillary	30	Vigila 2CR	Dual	210	7.6
6	Primary	Σ	62	IHD, HTN, AF, DM	33	т	Cephalic	23	Vigila 1CR	Single	135	6.4
<i>Vote</i> : Pati Abbreviat	ents are num ions: AF, atria	bered chro	onologica on; BMI,	ully according to the time o body mass index; CDK, ch	of the inition ronic kidr	ial implant. ney disease; COPD, o	chronic obstructi	ve pulmonary	/ disease; DCM, dilated car	diomyopat.	hy; DM, diabetes mell	itus;

TABLE 4 Summary of the premature ICD lead failure cohort

HTN, hypertension; IBD, inflammatory bowel disease; ICD, implantable cardioverter defibrillator; IHD, ischemic heart disease; LVEF, left ventricular ejection fraction; RA, rheumatoid arthritis.

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**FIGURE 5** Examples of radiographic images from fluoroscopy stored at the time of implantation for patients who subsequently experienced lead failure. The numbering of patients corresponds to the order of implantation and the numbering in Table 4. (A) Corresponding to Patient 2. (B) and (C) Corresponding to Patient 3. (D) Corresponding to Patient 4. (E) Patient number 5. (F) Patient 6. (G) Patient number 7 with tortuosity of the innominate vein. (H) Venogram of Patient 8 demonstrating a large cephalic vein (dotted arrow) which was not used; instead, the system was implanted by lateral axillary puncture (solid arrow). (I) Corresponding to Patient 9

underestimation of lead failure, although the open-access pacing clinic accounted for this to reasonable effect. Due to relatively smaller sample size for non-cephalic access, propensity matching could not be performed.

# 5 | CONCLUSION

Cephalic vein access for multi-lead ICD therapy is not a significant risk factor for lead failure in the long-term. Our data confirm that female gender and BMI are predictors of lead failure.

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#### CONFLICT OF INTERESTS

Dr. Mark M. Gallagher has acted as a consultant and a paid speaker for Boston Scientific and Cook Medical.

# DATA AVAILABILITY STATEMENT

Data available upon reasonable request.

#### ORCID

Mark M. Gallagher D http://orcid.org/0000-0002-6333-6420

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#### SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.

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