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Left atrial appendage closure device outcomes among cirrhosis patients with atrial fibrillation: a United States National Cohort Study

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Aims

Literature regarding outcomes associated with atrial fibrillation among cirrhosis patients who had left atrial appendage occlusion (LAAO) device procedure is limited. We aim to evaluate the in-hospital clinical outcomes and 30-day readmissions among LAAO with and without cirrhosis.

Methods and results

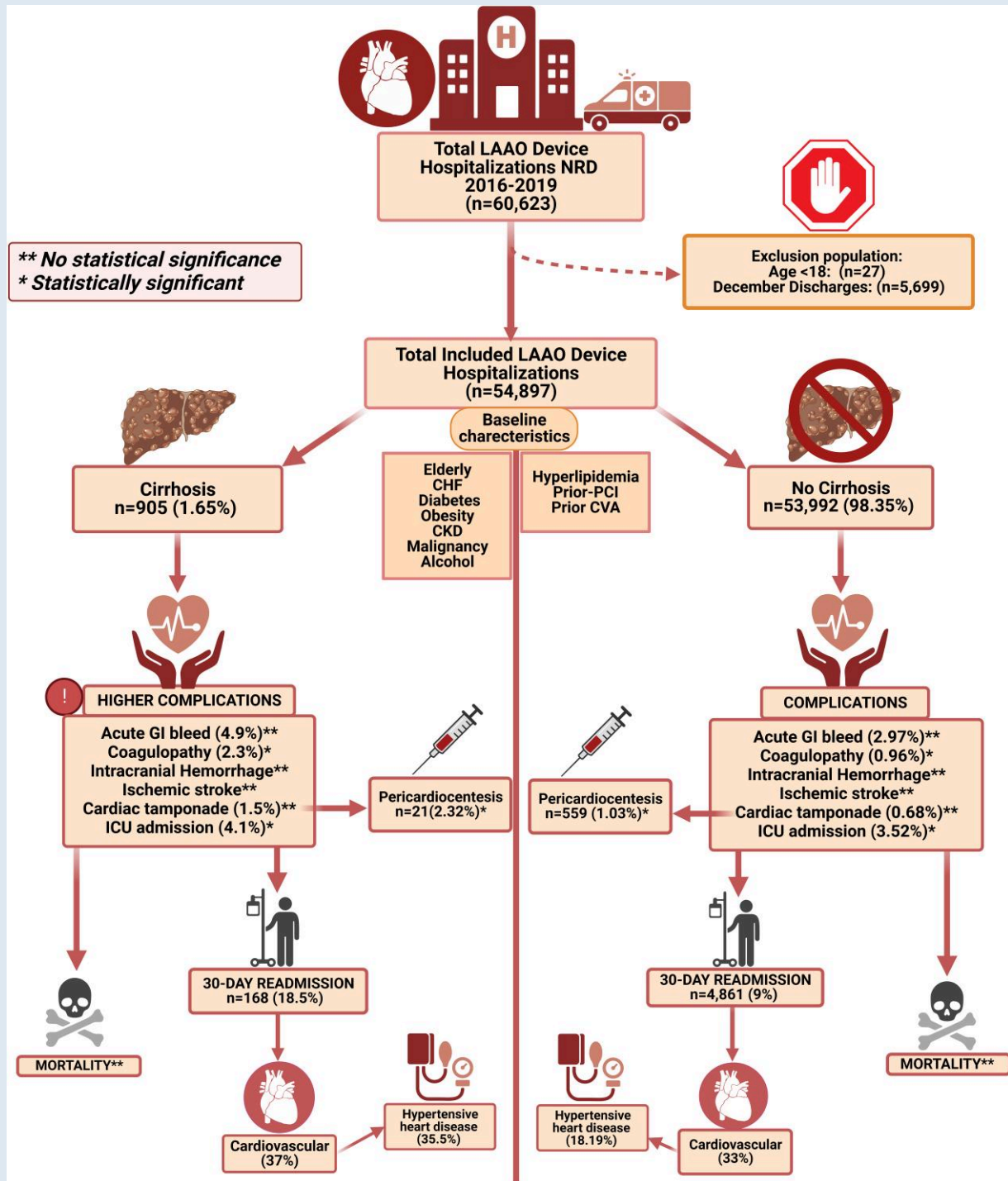
We performed a retrospective study of all hospitalizations associated with the LAAO procedure, using the Nationwide Readmissions Database for the years 2016–19. Primary outcomes were in-hospital clinical outcomes and 30-day readmissions. A total of 54 897 index hospitalizations for LAAO (female 41.8%) were reported. Of these, 905 (1.65%) had cirrhosis. Gastrointestinal (GI) bleeding was reported in 44 (4.9%) vs. 1606 (2.97%) and coagulopathy in 21 (2.3%) vs. 521 (0.96%) in cirrhosis and without-cirrhosis groups, respectively. A total of 872 (1.59%) patients needed blood transfusion, 24 (2.7%) vs. 848 (1.57%) in cirrhosis vs. without-cirrhosis groups ($P=0.047$). Fresh frozen plasma (FFP) transfusion was reported among 888 (1.62%), with cirrhosis 26 (3%) vs. without cirrhosis 862 (1.6%) ($P=0.05$). On adjusted multivariate logistic regression analysis, acute kidney injury, coagulopathy, FFP transfusion, and blood transfusion were strongly associated with cirrhosis, and GI bleeding, ischaemic stroke, and intracranial haemorrhage were not associated with cirrhosis. Readmissions in 30 days were 5028 (9.18%), 167 (18.5%) in the cirrhosis group and 4861 (9%) without-cirrhosis group ($P=0.01$). On multivariate Cox regression, CHA₂DS₂-Vasc score of six was significantly associated with 30-day readmission compared with other scores [hazard ratio 2.24; 95% confidence interval (1.58–3.16); $P<0.001$].

Conclusion

Left atrial appendage occlusion procedure in patients with cirrhosis had relatively similar GI bleeding and stroke rates, however, had higher rates of 30-day readmission. A higher CHA₂DS₂-Vasc score was more likely to be associated with 30-day readmissions and hence would help in discharge planning. The long-term safety and efficacy of LAAO in the cirrhosis population need to be demonstrated.

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Graphical Abstract



Keywords

Cirrhosis • Atrial fibrillation • Clinical outcomes • Coagulopathy • readmissions • LAAO

What's new?

- Cirrhosis patients who had left atrial appendage occlusion procedures had similar rates of gastrointestinal bleeding as patients without cirrhosis.
- There was no significant difference in stroke and intracranial haemorrhage between patients with and without cirrhosis.
- Higher rates of pericardiocentesis were reported among patients with cirrhosis.
- CHA₂DS₂-Vasc score was significantly associated with 30-day re-admission, the higher the score the more was the association.

Introduction

Atrial fibrillation (AF) is the most common cardiac arrhythmia encountered in clinical practice.¹ Atrial fibrillation is associated with a significantly higher risk of stroke, and strokes related to AF cause more disability when compared with non-AF-related strokes. Autopsy studies have shown that greater than 90% of patients who have a stroke associated with AF have a left atrial appendage (LAA) thrombus, thus necessitating the use of anticoagulants to mitigate this risk.^{2,3} There are varied data on the effect of anticoagulation among patients with cirrhosis and bleeding outcomes.^{4,5}

More recently, percutaneous LAA occlusion (LAAO) device has shown promise in mitigating the stroke risk in selected AF patients especially those patients at risk for anticoagulation.^{6–8} More importantly, AF patients with concurrent chronic liver disease such as cirrhosis are vital as they have both an increased risk of developing acute ischaemic stroke due to procoagulant state, hypoperfusion, diabetes, and dyslipidaemia and the risk of major bleeding with the use of oral anticoagulation therapy, secondary to a reduction in the synthesis of several clotting factors. Left atrial appendage occlusion device can be beneficial in this patient population, though major trials had excluded patients with liver cirrhosis.⁹

Unfortunately, major trials that led to the approval of this device did not have a sizeable portion of patients with underlying cirrhosis for this subset to be truly representative.^{6,7} We aim to assess the clinical outcomes of patients with AF undergoing LAAO who have concomitant cirrhosis of liver from a large nationally representative and contemporary sample of the US population.

Methods

Study population and inclusion criteria

This is an observational cohort study of LAAO device implantation-related hospitalizations for the years 2016–19 from the National Readmissions Database (NRD). The database was obtained from the Agency for Healthcare Research and Quality's (AHRQ) Healthcare Cost and Utilization Project (HCUP). The NRD is the largest publicly available all-payer inpatient care database in the United States and contains discharge-level data that participate in the HCUP project. National Readmissions Database represents 49.1% of total US hospitalizations. Patients can be tracked using these linkage numbers for readmission within the same calendar year. The database provides deidentified information about the patients' demographics and hospital-based information. Besides, it provides information about the days to readmission and readmission status.¹⁰ Since a publicly available database was used with deidentified patient information, the study was considered exempt from obtaining permission from the institutional review board. However, it was performed according to the ethical criteria set up by HCUP.^{10,11}

Patient and hospital characteristics

Baseline patient demographic characteristics (age, sex, insurance payer) were extracted using NRD variables. Diagnostic codes were used to

identify hypertension, diabetes mellitus, hyperlipidaemia, obesity, smoker, congestive heart failure (CHF), peripheral vascular disease, chronic obstructive pulmonary disease (COPD), AF, prior history of stroke, prior percutaneous coronary intervention (PCI), prior coronary artery bypass grafting, and prior myocardial infarction. Cardiovascular procedures were extracted by International Classification of Diseases 10 (ICD-10) procedural classification system codes. The procedures included the LAAO device implantation procedure.

We also extracted recorded data for associated complications, designated by the secondary discharge diagnosis, associated with each hospitalization duration in terms of acute kidney injury (AKI), ventricular fibrillation/ventricular tachycardia, cardiac tamponade, need for pericardiocentesis, acute heart failure, acute respiratory failure, stroke/transient ischaemic attack (TIA), ICU admission, need for fresh frozen plasma (FFP) infusion, need for blood transfusion, coagulopathy, intracranial haemorrhage (ICH), and gastrointestinal (GI) bleeding. We also calculated the current use of anticoagulation. All these numbers were extracted by using ICD-10 codes (see [Supplementary material online, File S1](#)).

Study definitions

Left atrial appendage occlusion was extracted using ICD-10 procedure codes '02L73DK'(Occlusion of Left Atrial Appendage with Intraluminal Device, Percutaneous Approach). A total of 60 623 index hospitalizations for the LAAO device procedure were recorded. Patients younger than 18 years ($n = 27$) and patients discharged in December of each calendar year ($n = 5699$) were excluded. A total of 54 897 index hospitalizations of LAAO device procedure encounters were extracted ([Figure 1](#)). ICD codes used are in [Supplementary material online, File S1](#).

Outcomes

The primary objective of the present analysis was to assess complications including cardiac tamponade, need for pericardiocentesis, GI bleeding, coagulopathy, strokes, and 30-day readmissions associated with LAAO devices among patients with cirrhosis.

Statistical methods

Categorical variables were expressed as weighted values and percentages, whereas continuous variables were expressed as mean \pm standard deviation if the variable was not skewed otherwise as median with 25th and 75th percentiles. We observed data were negatively skewed for age and hence were reported as median. Descriptive statistics were performed for demographics and comorbidities that were stratified by cirrhosis and compared with patients who did not have cirrhosis. We performed Pearson's χ^2 test for categorical variables and the t -test for continuous variables. We performed a multivariate logistic regression adjusted for model A which included age, diabetes, CHF, obesity, prior PCI, CKD, hyperlipidaemia, hypertension, alcohol, and cancer, and sequentially introduced each complication to see the association with cirrhosis (see [Supplementary material online, Tables S1–S6](#)).

We calculated the rates of 30-day readmission and stratified them into subgroups for with and without cirrhosis. We calculated the primary systemic causes for 30-day readmission. We also evaluated the most common cause for readmission within 30 days among the two subgroups.

We evaluated the major CHA₂DS₂-Vasc score on index and 30-day readmissions and compared using Pearson's χ^2 test between subgroups with and without cirrhosis. We computed the hazard ratio (HR) with a 95% confidence interval (CI) for the association of 30-day readmission with cirrhosis in a multivariate Cox regression analysis after adjusting for model B which included, CKD, COPD, teaching status of the hospital, urban location, hyperlipidaemia, smoking, obesity, and CHA₂DS₂-Vasc score.

All analyses were weighted analyses. Statistical analysis was performed using STATA version 16.1 (College Station, TX, USA). All P -values were two-sided, with a significance threshold of $P \leq 0.05$.

Results

A total of 54 897 index hospitalizations of LAAO device procedure encounters [median age: cirrhosis 71 (67–77) and without cirrhosis 77

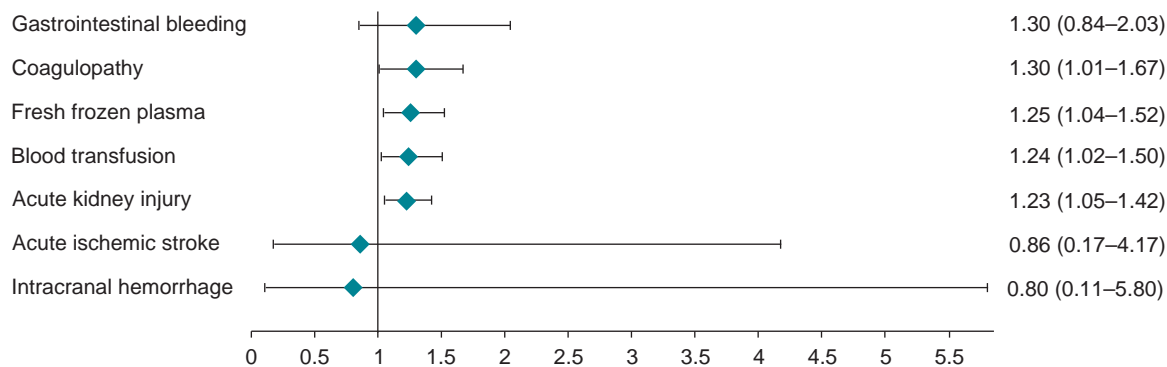


Figure 1 Adjusted multivariate logistic regression representing OR and 95% CI for association of complications with cirrhosis. CI, confidence interval; OR, odds ratio.

(71–82; female 41.8%] were reported for the years 2016–19 in NRD. Of these, a total of 905 (1.65%) had cirrhosis (*Graphical Abstract*). The baseline characteristics of the patients in the two groups are shown in *Table 1*. Patients who had cirrhosis were mostly men who had higher rates of comorbidities including CHF, diabetes, obesity, CKD, cancer, and alcohol use, whereas patients without cirrhosis had higher rates of hyperlipidaemia, prior PCI, and a history of stroke. Most patients had a CHA₂DS₂-Vasc score of 3 (25 358; 42.6%). Of these, 478 (52.9%) were in the cirrhosis subgroup and 24 880 (46.1%) were in the non-cirrhosis subgroup. Most patients were admitted to teaching hospitals in urban areas, and Medicare was the primary payer.

Clinical outcomes

Gastrointestinal bleeding was reported in 1650 (3%) encounters, 44 (4.9%) in the cirrhosis group and 1606 (2.97%) in the without-cirrhosis group ($P=0.05$). Coagulopathy was reported in 542 (1%) patients, 21 (2.3%) in the cirrhosis group vs. 521 (0.96%) in the without-cirrhosis group ($P=0.03$). Intracranial haemorrhage was reported in 130 (0.24%) patients and there was no significant difference between the two groups ($P=0.5$). Similarly, ischaemic stroke/TIA was reported among 356 (0.65%), with no significant difference between the two groups ($P=0.99$). A total of 872 (1.59%) patients needed blood transfusion during these encounters, 24 (2.7%) in the cirrhosis group compared with 848 (1.57%) in the without-cirrhosis group $P=0.047$. Fresh frozen plasma transfusion was reported among 888 (1.62%), 26 (3%) in the cirrhosis group vs. 862 (1.6%) in the without-cirrhosis group ($P=0.05$). A total of 1940 (3.53%) patients needed admission to the ICU. Of these, 37 (4.1%) were among the cirrhosis group and 1903 (3.52%) were among the without-cirrhosis group ($P=0.5$). Long-term (current use of) anticoagulation status was reported in 396 (43.8%) among the cirrhosis group compared with 25 901 (48%) among the without-cirrhosis group; $P=0.07$.

There was reported cardiac tamponade in 14 (1.53%) cirrhosis patients and 367 (0.68%) without-cirrhosis patients ($P=0.09$). All-cause pericardiocentesis was performed among 21 (2.32%) cirrhosis patients and 559 (1.03%) without-cirrhosis patients ($P=0.04$). A total of 1268 (2.3%) patients had AKI reported during the hospitalization encounters, 52 (5.7%) in the cirrhosis group vs. 1215 (2.25%) in the without-cirrhosis group ($P=0.001$). The detailed clinical outcomes are given in *Table 2*.

On multivariate logistic regression analysis adjusted for model A variables, AKI [odds ratio (OR) 1.23, 95% CI 1.05–1.42; $P=0.007$], coagulopathy (OR 1.300, 95% CI 1.01–1.67; $P=0.03$), FFP transfusion (OR 1.25, 95% CI 1.04–1.52; $P=0.01$), and blood transfusion rates (OR

1.24, 95% CI 1.02–1.50; $P=0.02$) were strongly associated with cirrhosis. On the other hand, GI bleeding (OR 1.30, 95% CI 0.84–2.03; $P=0.23$), stroke/TIA (OR 0.86, 95% CI 0.17–4.17; $P=0.85$), and ICH (OR 0.80, 95% CI 0.11–5.80; $P=0.82$) had no significant association with cirrhosis. The results are also given in *Figure 1*.

Readmission analysis

A total of 5028 (9.18%) patients were readmitted within 30 days of discharge among live discharges. A total of 167 (18.5%) patients were readmitted within 30 days of discharge in the cirrhosis group. The predominant primary cause for readmission was cardiovascular related [62 (37%)] with hypertensive heart disease and heart failure being the primary diagnosis in 22 (35.5%) patients. Among the non-cirrhosis group, 4861 (9%) were readmitted within 30 days of discharge among live discharges. The predominant primary cause for readmission was cardiovascular related (33%). The predominant primary cause was hypertensive heart disease and heart failure, 642 (18.19%). A system-wise breakdown of the primary cause for readmission in 30 days is shown in *Figure 2*. The majority of patients readmitted in 30 days were having CHA₂DS₂-Vasc score of 3. On multivariate Cox regression adjusted for model B variables, CHA₂DS₂-Vasc score of 6 was significantly associated with 30-day readmission compared with other scores (HR 2.24, 95% CI 1.58–3.56, $P<0.001$) (see *Supplementary material online, Table S7*).

Discussion

Our analysis of outcomes of LAAO procedures using a contemporary real-world dataset revealed higher complication rates in those with cirrhosis compared with patients without cirrhosis. The complications include the need for pericardiocentesis, requirements for transfusion of blood products, and AKI being higher in the cirrhosis group compared with the without-cirrhosis group. There was no difference in GI bleeding between the groups in the adjusted analysis. There was no difference in the current use of anticoagulation status between the groups. Patients with cirrhosis had higher rates of 30-day readmissions than those without cirrhosis. CHA₂DS₂-Vasc score was a significant predictor of 30-day readmission with a higher score associated with a higher risk for 30-day readmissions.

Bleeding is one of the major complications associated with cirrhosis. The predisposition to bleeding is secondary to derangements in coagulation factors and thrombocytopenia secondary to cirrhosis.¹² The use of oral anticoagulants may further worsen the risk of bleeding among

Table 1 Baseline characteristics of LAAO device implantation encounters, stratified by presence or absence of cirrhosis

	Cirrhosis with LAAO device (n = 54 897)		
	Cirrhosis	No cirrhosis	P-value
I. No. of observations (weighted) (%)	905 (1.68%)	53 992 (98.3%)	
II. Demographic characteristics			
Age	72 (67, 77)	77 (71, 82)	<0.001
Female—No. (%)	352 (38.9%)	22 577 (41.8%)	0.17
III. Risk factors and comorbidities—No. (%)			
Diabetes mellitus	460 (50.8%)	18 909 (35%)	<0.001
Dyslipidaemia	475 (52.5%)	33 742 (62.5%)	<0.001
Peripheral vascular disease	56 (6.2%)	4473 (8.28)	0.0662
Chronic obstructive pulmonary disease	146 (16.1%)	8843 (16.4%)	0.8779
Congestive heart failure	330 (36.5%)	14 192 (26.3%)	<0.001
Hypertension	789 (87.3%)	46 789 (86.7%)	0.6831
Smoker	341 (37.7%)	18 509 (34.3%)	0.1182
Obesity	212 (23.5%)	9226 (17.1%)	0.0004
Chronic kidney disease	286 (31.7%)	12 937 (24%)	0.0001
Prior percutaneous coronary intervention	100 (11.1%)	9274 (17.2%)	0.0001
Prior coronary artery bypass grafting	118 (13%)	7537 (14%)	0.5680
Prior myocardial infarction	112 (12.4%)	6601 (12.2%)	0.8896
Prior cerebrovascular accident	175 (19.4%)	13 236 (24.5%)	0.0029
Asthma	50 (5.54%)	2575 (4.77%)	0.4395
Alcohol abuse	205 (22.7%)	537 (0.99%)	<0.001
Malignancy	411 (45.4%)	13 055 (24.2%)	<0.001
IV. Hospital demographics—No. (%)			
Urban hospital	905 (100%)	53 990 (100%)	0.3
Teaching hospital	787 (87%)	46 984 (87%)	0.97
Insurance status			
Medicare	768 (86.6%)	48 540 (91%)	
Medicaid	36 (4%)	518 (0.97%)	
Private	80 (9%)	3959 (7.42%)	

LAAO, left atrial appendage occlusion.

Table 2 Clinical outcomes associated with index hospitalization for LAAO device implantation, stratified by presence or absence of cirrhosis

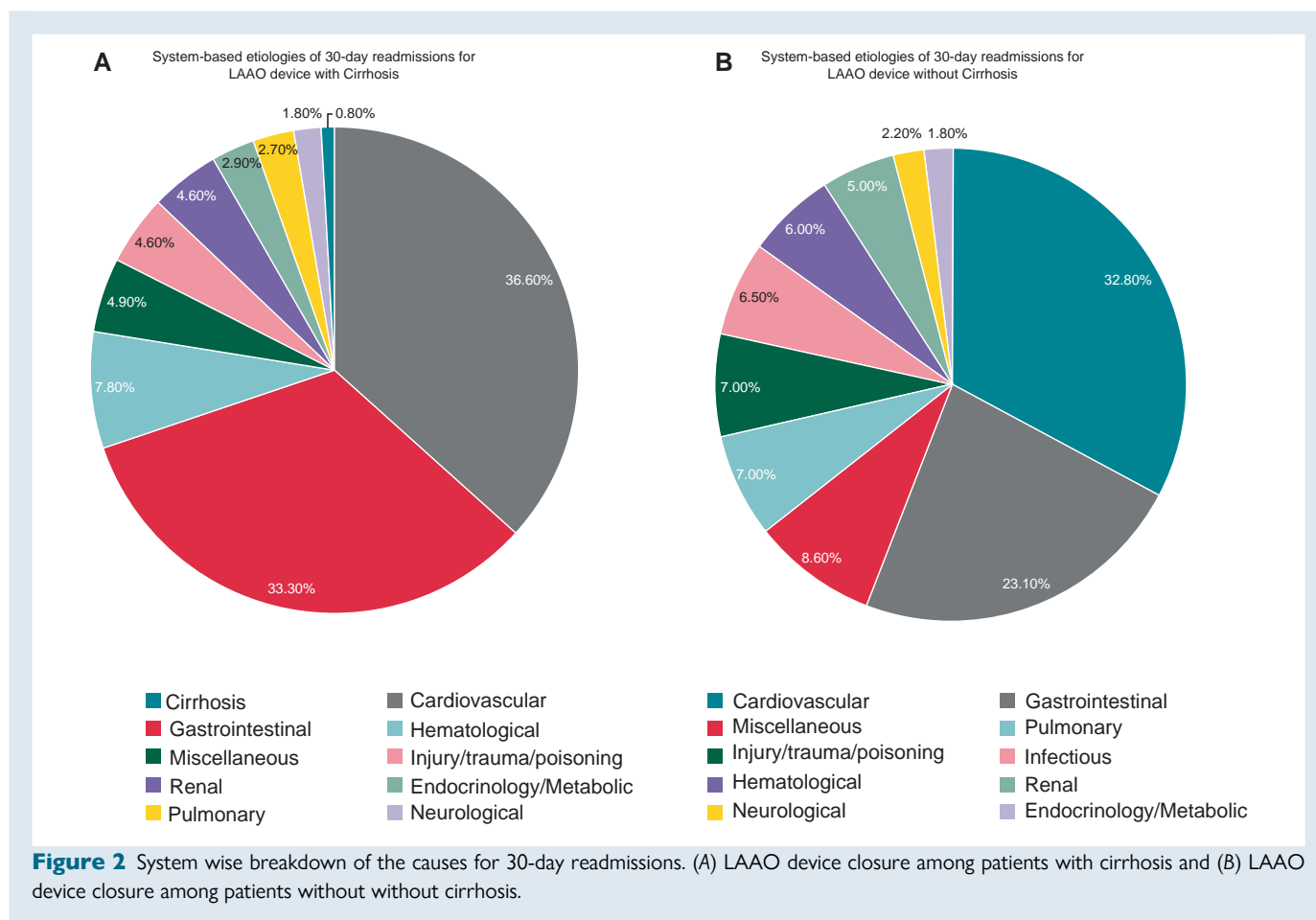
	LAAO device (n = 54 897)		
	Cirrhosis	No cirrhosis	P-value
	905 (1.68%)	53 992 (98.3%)	
Acute kidney injury	52 (5.69%)	1215 (2.25%)	0.001
VT/VF	11 (1.23%)	792 (1.47%)	0.66
Heart block	35 (3.91%)	2189 (4.06%)	0.86
Bradycardia	12 (1.32%)	848 (1.57%)	0.61
Respiratory failure	19 (2.11%)	1049 (1.94%)	0.78
CHA ₂ DS ₂ -VASc:			
Score 1	31 (3.37%)	1230 (2.28%)	
Score 2	123 (13.6%)	7473 (13.8%)	
Score 3	478 (52.9%)	24 880 (46.1%)	
Score 4	38 (4.22%)	2820 (5.22%)	
Score 5	188 (20.8%)	15 759 (29.2%)	
Score 6	47 (5.2%)	1830 (3.39%)	
GI bleeding	43 (4.83%)	1606 (3.0%)	0.05
Coagulopathy	21 (2.28%)	521 (0.97%)	0.03
Acute blood loss anaemia	24 (2.6%)	1044 (1.93%)	0.28
Intensive care unit	37 (4.11%)	1903 (3.52%)	0.5
Blood transfusion	24 (2.7%)	848 (1.57%)	0.047
FFP transfusion	26 (2.92%)	862 (1.6%)	0.05

FFP, fresh frozen plasma; GI, gastrointestinal; LAAO, left atrial appendage occlusion; VT/VF, ventricular fibrillation/ventricular tachycardia.

cirrhosis patients with AF. Such events are associated with significant mortality and morbidity rates of 5–15%.^{13–15} The prevalence of GI bleeding among AF patients on anticoagulation is 1–3%.¹⁶ Prior studies have reported higher bleeding rates in patients with AF and cirrhosis (6.89%).⁴ We observed a prevalence of GI bleeding among 3% in the overall cohort, higher among the cirrhosis group (4.9%) than among the without-cirrhosis group (2.97%; $P=0.05$); however, on adjusted analysis, there was no significant difference in GI bleeding between the groups. Similarly, we observed higher rates of coagulopathy

(2.3%) in the cirrhosis group than the non-cirrhosis group (0.96%; $P=0.03$). This could be the reason for the need for transfusion of blood products among cirrhosis patients observed in our analysis. Despite higher rates than the without-cirrhosis LAAO group, the bleeding and coagulopathy rates were much lower than earlier reported in AF with cirrhosis population.⁴ This could be due to a few reasons as we outline below. First, the low event rates and short duration of follow-up could have resulted in a type II error. Second, improving operator experience with LAAO implantation could have resulted in lower complications. Third, selection bias could have led to the selection of cirrhotic patients who may have been at lower risk for bleeding. Finally, there is a significant deviation in the choice of post-procedure therapy in terms of antiplatelet and anticoagulant use from the regimen used in pivotal trials that led to LAAO device approval.

A meta-analysis of 12 415 patients reported a periprocedural rate of 2.3% pericardial effusion, of which 1.2% had tamponade, among patients who had LAAO device implantation.¹⁷ Another study from the United States National inpatient sample for 5175 procedures for the year 2016 reported a 0.29% pericardial surgery rate and 0.68% pericardiocentesis rate.¹⁸ Cardiac tamponade was reported among 0.7% of our patient population with no significant difference among the groups. However, we observed a significantly higher rate of pericardiocentesis in the cirrhosis group (2.32%) than the without-cirrhosis group (1.03%) ($P=0.003$). Cirrhosis is known to cause pericardial effusion with a reported rate of 63% among decompensated cirrhosis patients.¹⁹ This could be the reason for higher rates of pericardiocentesis among the group.



Higher rates of AKI were observed in our study among cirrhosis patients than those without cirrhosis. Acute kidney injury is a known complication associated with cirrhosis.²⁰ The aetiology for the increased incidence of AKI needs further exploration. Hepato-renal interactions, the use of diuretics in patients with ascites, beta-blockers for portal hypertension, and the use of general anaesthesia can predispose patients to intraprocedural hypotension leading to AKI.

We observed a 30-day readmission rate of 9.18% in the overall cohort, with significantly higher readmission rates in the cirrhosis group (18.5%) than in the without-cirrhosis group (9%). A retrospective study from the NRD for the years 2016–18 reported 30-day readmission rates for patients who had LAAO devices of 9.2%.²¹ Although data regarding the readmission rates in cirrhosis with LAAO device are scarce, it can be hypothesized that higher readmissions in cirrhosis can be explained by higher rates of complications experienced by cirrhotic patients compared with non-cirrhotic patients. A previous study showed that the 30-day readmission rate was 17% in cirrhotic patients, with complications such as portal hypertension (47%) and infections (17%) accounting for the majority of the cases.²²

Interestingly, CHA₂DS₂-Vasc score was associated with 30-day readmission and the association was higher with higher score. A retrospective study from NRD for the year 2013 on AF patients reported higher readmission rates with increasing CHA₂DS₂-Vasc score.²³ A recent study showed the presence of three components of CHA₂DS₂-Vasc score such as older age, heart failure, and Type 2 diabetes to be associated with prohibitive risk with a 50% mortality after LAAO at 1 year.²⁴ These findings would suggest that not only careful discharge planning especially among patients with high CHA₂DS₂-Vasc scores but an emphasis on careful patient selection for LAAO in the first

place is perhaps more important. Not surprisingly, GI-related admissions were significantly higher in the cirrhosis group compared with the without-cirrhosis group (33% compared with 23%).

Our study has several limitations, including being a retrospective, observational study, and inference regarding causation should be made with caution as we were unable to control for comorbidities. Also, the study is based on reported ICD-10 codes to identify diagnoses, and these may not be entirely accurate. The NRD may have inaccurate over-coding or underreporting of some comorbid diagnoses. The dataset lacks information related to medications including medications such as antiplatelets, diagnostic imaging, and laboratory results. However, since the population is patients who had LAAO procedures, we believe the anticoagulation history should be similar. Imaging parameters such as device-related thrombus and para-device leak could not be assessed. A selection bias is likely in those patients with cirrhosis who underwent the LAAO procedure. However, NRD and the codes used in this study have been applied in multiple clinical studies and can be considered a highly reliable database, and given the large cohort analysed, this minimizes the study limitation.

Conclusions

Left atrial appendage occlusion procedure in patients with cirrhosis appears to be relatively safe despite the higher incidence of AKI and the need for pericardiocentesis. However, there were no significant differences in complications including ICH, GI bleeding, or ischaemic stroke in patients with cirrhosis compared with those without cirrhosis who underwent the LAAO procedure. Cirrhosis patients had higher rates

of 30-day readmission. A higher CHA₂DS₂-Vasc score was associated with a higher risk of 30-day readmission. More studies are needed to demonstrate the short-term and long-term efficacy and safety of LAAO in patients with cirrhosis who have traditionally been excluded from pivotal trials.

Supplementary material

Supplementary material is available at *Europace* online.

Conflict of interest: None of the authors have any conflicts of interest to disclose.

Data availability

The data is available on HCUP database which is publicly available.

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