



## ORIGINAL RESEARCH

# Evaluation of Gastroparesis After Radiofrequency Catheter Ablation of Atrial Fibrillation

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### Abstract

**Objective:** Gastroparesis-related symptoms are common after catheter ablation of atrial fibrillation (AF). In the present study, patients were evaluated in terms of gastroparesis after AF ablation using the Gastroparesis Cardinal Symptom Index (GCSI) scale.

**Methods:** 85 consecutive patients (age 59 years, 57 women [67%]) with paroxysmal AF who submitted for catheter ablation were included in this cross-sectional study. Radiofrequency Catheter Ablation Procedure was applied to all patients. The study population was evaluated by GCSI score at baseline and after 1 month of follow-up after catheter ablation. GCSI score was determined by averaging the mean score of 3 subscales: postprandial fullness/early satiety (4 items), nausea/vomiting (3 items), and bloating (2 items).

**Results:** The GCSI total score was 0.6 at baseline and 0.8 at the 1-month follow-up visit after ablation ( $p < 0.001$ ). Mean GCSI scores varied significantly by severity of vomiting

( $p < 0.001$ ), nausea ( $p < 0.016$ ), stomach fullness ( $p < 0.001$ ), not able to finish meal and feeling full after meals ( $p < 0.001$ ). Recurrence of AF developed in 19% (16 of 85) of patients at one-year follow-up. The study population was divided into 2 subgroups according to the presence of AF recurrence. A statistically significant increase was observed in GCSI score after ablation in both groups.

**Conclusions:** The findings of the present study showed that treatment of AF with ablation resulted in a statistically significant increase in gastroparesis symptoms independent of recurrence. The present study suggested that the GCSI scale may be a cost-saving screening test for rapid diagnosis and proper treatment.

**Keywords:** Atrial fibrillation, gastroparesis, gastroparesis cardinal symptom index, radiofrequency ablation.

## Introduction

Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia in adults.<sup>1</sup> With the developing technology, AF ablation has come to the fore in patients who are planned to control rhythm in paroxysmal and persistent AF. AF catheter ablation demonstrates its main clinical benefit by providing relief from arrhythmia-related symptoms.<sup>2</sup> Although the rate of procedure-related complications in AF ablation treatment is 7.8%, this rate was lower in experienced centers.<sup>3,4</sup>

One of these complications is gastroparesis, which clinically manifests with symptoms such as epigastric discomfort, abdominal pain, nausea, vomiting, and bloating. The possible mechanism is thought to be due to the injury of the periesophageal vagus nerve, depending on the anatomical neighborhood.<sup>5</sup> The incidence of gastroparesis after AF ablation differ in studies because of some symptoms is uncertain and difficult to measure.<sup>6</sup> Moreover, its incidence may be underestimated because of the cost of diagnosis.

Gastroparesis Cardinal Symptom Index (GCSI) is a valid, non-invasive, cost-saving test used to diagnose and measure symptom severity in patients with gastroparesis.<sup>7</sup> The present study aimed to evaluate the rate of gastroparesis with GCSI test in patients undergoing AF ablation.

## Materials and Methods

### Study Population

This cross-sectional study was conducted in a single center. PAF was defined as two or more AF episodes lasting less than 7 days over the last 12 months and terminating spontaneously. All the patients were symptomatic and had failed to respond to beta-blockers or antiarrhythmic agents (AAD). Assuming an alpha of 0.05, a power of 0.80, and with 16% estimated rate in line with the previous reports, the estimated sample size was at least 84 patients in total.” A total of 85 consecutive patients who underwent catheter ablation for Paroxysmal Atrial Fibrillation (PAF) were enrolled in this study. The study was conducted at tertiary referral hospital (Bursa, Turkey) between January 2022 and December 2022.

The exclusion criteria of this study were as follows: 1) ischemic cardiomyopathy, valvular heart disease, left ventricular hypertrophy and other cardiomyopathies 2) history of gastric surgery or cancer of the gastrointestinal tract 3) sleep apnea syndrome 4) chronic obstructive pulmonary disease and 5) known psychiatric disorders 6) history of cholecystectomy surgery.

Demographic, clinical, and laboratory characteristics of the study patients were recorded from patient files. Details of the study were explained to patients and written informed consent was obtained before participation. The study protocol was approved by the local institutional ethics committee.

### Radiofrequency Catheter Ablation Procedure (RFCA)

All RFCA procedures were performed by a single operator team. In brief, transesophageal echocardiography was performed within 24 hours before the procedure to determine the structure of the interatrial septum, and to exclude the presence of a potential left atrial (LA) thrombus. Conscious sedation was performed using boluses of midazolam and fentanyl during the ablation procedure. First, a decapolar catheter was placed in the coronary sinus using left femoral venous access. Double transseptal puncture was performed under fluoroscopic guidance. Esophageal monitoring was not performed during the ablation procedure. A circumferential mapping catheter (CMC; Lasso™; Biosense Webster) was placed in the LA using an 8.5 Fr SL1 length sheath. Next, the contact force (CF)-sensing ablation catheter (Thermocool® SmartTouch, Biosense Webster, Inc.) was advanced into the LA simultaneously with the CMC using a second 8.5 Fr SL1 long sleeve. Reconstruction and mapping of pulmonary veins (PVs) and LA was performed by the CMC and the ablation catheter using the CARTO® mapping system (Biosense Webster, Inc). The ablation strategy consisted of pulmonary vein isolation (PVI), which was defined as creating large radiofrequency (RF) circumferential lesion sets around both ipsilateral PVs with verification of conduction block. The circumferential lesions were created at the level of the PV-LA junctions (PV antrum) using the point-by-point technique. A temperature mode with 35-40 W power

(flow rate, 17–20 mL/min) was used. Lower power of 25-30 W (flow rate, 17 mL/min) and time settings were used to avoid esophageal damage and steam pop formation on the posterior LA wall and roof area. CF data were presented to the operator throughout the procedure. RF energy was delivered with a target CF of 10-40 g until a bipolar signal reduction of at least 70% was achieved. Successful PVI was defined as recording of both the entry and exit block (bidirectional block) for the four PVs after the ablation procedure. RF energy was delivered in the earliest potential recorded in the carina between the superior and inferior PVs if bidirectional block was not achieved with antral isolation. At the end of the procedure, a waiting period of at least 20 minutes was applied to evaluate the LA-PV connections, and then the bidirectional block was evaluated again.

#### Measurement of Gastroparesis Cardinal Symptom Index (GCSI):

GCSI is a self-assessment scale developed by Revicki et al.<sup>7</sup> to determine the effectiveness of medical treatments and for monitoring outcomes in gastroparesis. GCSI score was determined by averaging the mean score of 3 subscales: postprandial fullness/early satiety (4 items), nausea/vomiting (3 items), and bloating (2 items). The severity of the symptoms is questioned according to the clinical situation in the last two weeks. The GCSI total score is calculated as the average of the three symptom subscales. GCSI total score can range from 0 to 5, with higher scores to display greater symptom severity.

#### Follow-Up:

The study population was re-evaluated by electrocardiography (ECG), 2D transthoracic echocardiography and GCSI score after 1 month of follow-up after catheter ablation. Anti-arrhythmic treatment was used to prevent early recurrences in the first 3 months after ablation, which was defined as the blanking period. A 24-hour Holter ECG recording was performed at every 3-month visit. Recurrent AF was defined

as an AF episode lasting >30 seconds in the Holter or ECG recording.

#### Statistical Analysis

Statistical analyses were performed with the IBM SPSS package program (IBM Corp., Armonk, NY, USA). Normal distribution was evaluated with the Kolmogorov-Smirnov test. Normally distributed numerical variables were shown as mean  $\pm$  standard deviation, and non-normally distributed variables were shown as median (min-max). Categorical variables were expressed as numbers and percentages. Differences in numerical variables between groups were evaluated with Student's T-test or Mann-Whitney U test. Categorical variables were compared using Chi-square, Yates' correction and Fisher's exact tests. Changes in Gastroparesis Cardinal Symptom findings were performed by Wilcoxon test, McNemar test, and Marginal homogeneity test. In statistical analysis,  $p < 0.05$  (\*) values were considered significant.

## Results

The study population consisted of consecutive eighty-five patients. The average age was 59 years, and 67% (57 of 85) were women. Mean LA diameter and LA volume index in echocardiography were  $39.3 \pm 6.4$  mm and  $27.5 \pm 7.4$  mL/m<sup>2</sup>, respectively. As ablation technique, pulmonary vein isolation was preferred in 74 (87,1%) patients, and pulmonary vein isolation and posterior wall isolation were preferred in 11 (12,9%) patients. Mean procedure time was  $97,1 \pm 19,1$  minute. Baseline demographic and clinical findings of the study population were presented in [Table 1](#).

Scoring for each GCSI item ranged from 0 to 5. The substance properties for the nine GCSI items are summarized in [Table 2](#). In brief, the GCSI total score was 0.6 at baseline and 0.8 at the 1-month follow-up visit after ablation ( $p < 0,001$ ). Mean GCSI scores varied significantly by severity of vomiting ( $p < 0.001$ ), nausea ( $p < 0.016$ ), stomach fullness ( $p < 0.001$ ), not able to finish meal and feeling full after meals ( $p < 0.001$ ).

**Table 1.** Baseline demographic and clinical findings of the study population

Variables	All population n=85	Non-recurrence n=69	Recurrence n=16	p
Age (years)	58.9±10.8	58.3±10.4	61.3±12.5	0.316
Gender, n (%)				
Male	28(32.9)	23(33.3)	5(31.3)	0.999
Female	57(67.1)	46(66.7)	11(68.8)	
Weight (kg)	83.1±15.3	82.7±15.4	84.8±15.4	0.615
Height (cm)	161.1±9.0	161.4±9.1	159.6±8.8	0.454
Body mass index (kg/m <sup>2</sup> )	32.2±6.3	31.9±6.5	33.3±5.6	0.412
Diabetes mellitus, n (%)	22(25.9)	15(21.7)	7(43.8)	0.135
Hypertension, n (%)	45(52.9)	36(52.2)	9(56.3)	0.987
HAS-BLED score	1(0-3)	1(0-3)	1.5(0-3)	0.184
CHADVASC score	2(0-6)	2(0-6)	2.5(0-6)	0.133
Hb1c value (%)	6.3±1.2	6.2±1.0	7.0±1.7	0.073
High sensitive C-reactive protein (mg/L)	1.1(0.2-7.6)	1(0.2-3.5)	2.4(0.5-7.6)	0.002*
Sedimentation (mm/h)	18(3-69)	17(3-69)	22(6-56)	0.15
White blood cell (10 <sup>9</sup> / L)	7146.5±1834.7	7195.7±1891.7	6934.4±1602.6	0.611
Hemoglobin (g/dl)	13.4±1.6	13.5±1.6	13.1±1.4	0.334
Neutrophil (10 <sup>9</sup> / L)	4426.5±1485.3	4435.4±1549.8	4388.1±1209.7	0.91
Lymphocyte (10 <sup>9</sup> / L)	2088.8±621.9	2122.6±630	1943.1±581.7	0.301
Neutrophil/lymphocyte	2(0.9-8.7)	2(0.9-8.7)	2(1.4-5.9)	0.431
Thyroid stimulating hormone (TSH)	1.5(0-9.6)	1.4(0-9.6)	1.8(0.4-9.2)	0.443
Total cholesterol (mg/dl)	185.9±41.2	188.6±41.9	174.5±37.5	0.222
Triglycerides (mg/dl)	152.2±73.8	148±73.4	169.6±75.2	0.295
Low density lipoprotein (mg/dl)	110.4±36.1	112.1±36.9	103.2±32.8	0.376
High density lipoprotein (mg/dl)	46.6±10.1	47.1±10.4	44.5±9	0.62
Brain natriuretic peptide (pg/ml)	64(10-776)	62(10-776)	67(26-752)	0.493
Interventricular septal diameter (cm)	1(0.7-8.5)	1(0.7-8.5)	1(0.9-1.4)	0.888
Posterior wall diameter (cm)	1(0.7-7)	1(0.7-7)	1(0.9-1.3)	0.891
Left ventricle end-diastolic diameter (mm)	46.1±3.4	46±3.4	46.8±3.3	0.367
Left ventricle end-systolic diameter (mm)	31.2±4.1	31.3±4.3	31±3.3	0.791
Left ventricle ejection fraction (%)	59.3±4.2	59.5±4.2	58.3±4.3	0.302
E-wave (cm/min)	8.3±2	8.3±1.9	8.7±2.5	0.467
A-wave (cm/min)	6(0.9-11)	6(3-11)	6(0.9-10)	0.999
E/A	1.3(0.7-15.1)	1.3(0.7-4)	1.3(0.8-15.1)	0.924
Left atrial volume index (ml/m <sup>2</sup> )	27.5±7.4	26.3±6.8	32.7±8.1	0.002*
Therapy, n (%)				
Anticoagulant	61(71.8)	48(69.6)	13(81.3)	0.53
Antiarrhythmic	41(48.2)	31(44.9)	10(62.5)	0.27
Beta-blocker	56(65.9)	43(62.3)	13(81.3)	0.252
Calcium canal blockers	22(25.9)	18(26.1)	4(25.0)	0.999
Angiotensin Converting Enzyme inhibitor and receptor blocker	37(43.5)	30(43.5)	7(43.8)	0.999
Fluoroscopy time (min)	12(6-25)	12(6-25)	11.8(7-18)	0.55
Ablation technique, n (%)				
Pulmonary vein isolation (PVI)	74(87.1)	60(87.0)	14(87.5)	0.999
PVI + posterior wall isolation	11(12.9)	9(13.0)	2(12.5)	
Procedure time (min)	97.1±19.1	97.7±19.4	94.6±18.1	0.567

Numerical variables showing normal distribution were shown as mean±SD, and numerical variables not showing normal distribution were shown as median (min-max). Categorical variables were shown as numbers(%). \*p<0.05 indicates statistical significance.

**Table 2.** Gastroparesis Cardinal Symptom changes before and after ablation

Variables	All population n=85		P
	Pre-ablation	Post-ablation	
Gastroparesis Cardinal Symptom Index	0.6(0-1.4)	0.8(0-2.0)	<0.001*
Nausea, n(%)			
None	70(82.4)	56(65.9)	0.016*
Very mild	15(17.6)	29(34.1)	
Gagging, n(%)			
None	65(76.5)	77(90.6)	0.083
Very mild	20(23.5)	5(5.9)	
mild	-	3(3.5)	
Vomiting, n(%)			
None	85(100.0)	76(89.4)	<0.001*
Very mild	-	9(10.6)	
Stomach fullness, n(%)			
None	16(18.8)	3(3.5)	<0.001*
Very mild	47(55.3)	28(32.9)	
Mild	21(24.7)	27(31.8)	
Moderate	1(1.2)	24(28.2)	
Severe	-	3(3.5)	
Not able to finish meal, n(%)			
None	76(89.4)	11(12.9)	<0.001*
Very Mild	8(9.4)	46(54.1)	
Mild	1(1.2)	26(30.6)	
Moderate	-	1(1.2)	
Severe	-	1(1.2)	
Feeling full after meals, n(%)			
None	11(12.9)	9(10.6)	<0.001*
Very mild	47(55.3)	21(24.7)	
Mild	15(17.6)	42(49.4)	
Moderate	11(12.9)	8(9.4)	
Severe	1(1.2)	5(5.9)	
Loss of appetite, n(%)			
None	11(12.9)	15(17.6)	0.577
Very mild	56(65.9)	52(61.2)	
Mild	18(21.2)	17(20.0)	
Moderate	-	1(1.2)	
Bloating, n(%)			
None	24(28.2)	15(17.6)	0.093
Very mild	31(36.5)	61(71.8)	
Mild	28(32.9)	6(7.1)	
Moderate	2(2.4)	3(3.5)	
Belly or stomach visibly larger, n(%)			
None	72(84.7)	76(89.4)	0.480
Very Mild	12(14.1)	6(7.1)	
Mild	1(1.2)	3(3.5)	

Since the index and its subgroups do not show normal distribution, they are shown as median (min-max). Categorical variables were shown as numbers (%).

\*p<0.05 indicates statistical significance.

Recurrence of AF developed in 19% (16 of 85) of patients at one-year follow-up. The study population was divided into 2

subgroups according to the presence of AF recurrence. There were no differences of echocardiographic and procedural features. The baseline high sensitive C-reactive protein and LA volume index was higher in patients with AF

recurrence ( $p=0,002$ ). A statistically significant increase was observed in GCSI score after ablation in both groups. Detailed GCSI items by subgroups are summarized in Table 3.

**Table 3.** Gastroparesis Cardinal Symptom findings according to the presence of atrial fibrillation recurrence

Variables	Non-recurrence n=69		Recurrence n=16		p1	p2	p3	p4
	pre-ablation	post-ablation	pre-ablation	post-ablation				
Gastroparesis Cardinal Symptom Index	0.5 (0-1.4)	0.8 (0-1.9)	0.8 (0.3-1.1)	0.9 (0.5-1.8)	0.045*	0.006*	<0.001*	0.002*
Nausea, n(%)								
None	57(82.6)	47(68.1)	13(81.3)	9(56.3)	0.999	0.542	0.068	0.046*
Very mild	12(17.4)	22(31.9)	3(18.8)	7(43.8)				
Gagging, n(%)								
None	52(75.4)	63(91.3)	13(81.3)	14(87.5)				
Very mild	17(24.6)	3(4.3)	3(18.8)	2(12.5)	0.863	0.306	0.102	0.564
Mild	-	3(4.3)	-	-				
Vomiting, n(%)								
None	62(89.9)	69(100.0)	14(87.5)	16(100.0)	0.999	-	0.008*	0.157
Very mild	7(10.1)	-	2(12.5)	-				
Stomach fullness, n(%)								
None	16(23.2)	3(4.3)	-	-				
Very mild	38(55.1)	27(39.1)	9(56.3)	1(6.3)				
Mild	14(20.3)	20(29.0)	7(43.8)	7(43.8)	0.050*	0.038*	<0.001*	0.001*
Moderate	1(1.4)	16(23.2)	-	8(50.0)				
Severe	-	3(4.3)	-	-				
Not able to finish meal, n(%)								
None	61(88.4)	11(15.9)	15(93.8)	-				
Very Mild	7(10.1)	38(55.1)	1(6.3)	8(50.0)				
Mild	1(1.4)	18(26.1)	-	8(50.0)	0.999	0.232	<0.001*	<0.001*
Moderate	-	1(1.4)	-	-				
Severe	-	1(1.4)	-	-				
Feeling full after meals, n(%)								
None	11(15.9)	9(13.0)	-	-				
Very mild	39(56.5)	19(27.5)	8(50.0)	2(12.5)				
Mild	10(14.5)	33(47.8)	5(31.3)	9(56.3)	0.210	0.013*	<0.001*	0.059
Moderate	8(11.6)	3(4.3)	3(18.8)	5(31.3)				
Severe	1(1.4)	5(7.2)	-	-				
Loss of appetite, n(%)								
None	11(15.9)	15(21.7)	-	-				
Very mild	43(62.3)	39(56.5)	13(81.3)	13(81.3)	0.210	0.133	0.532	0.999
Mild	15(21.7)	14(20.3)	3(18.8)	3(18.8)				
Moderate	-	1(1.4)	-	-				
Bloating, n(%)								
None	22(31.9)	15(21.7)	2(12.5)	-				
Very mild	25(36.2)	47(68.1)	6(37.5)	14(87.5)	0.231	0.020*	0.170	0.317
Mild	21(30.4)	6(8.7)	7(43.8)	-				
Moderate	1(1.4)	1(1.4)	1(6.3)	2(12.5)				
Belly or stomach visibly larger, n(%)								
None	59(85.5)	61(88.4)	13(81.3)	15(93.8)				
Very Mild	10(14.5)	6(8.7)	2(12.5)	-	0.280	0.354	0.999	0.157
Mild	-	2(2.9)	1(6.3)	1(6.3)				

Since the index and its subgroups do not show normal distribution, they are shown as median (min-max). Categorical variables were shown as numbers (%). \* $p<0.05$  indicates statistical significance. P1: Pre-ablation, Non-recurrence vs recurrence, P2: Post-ablation, Non-recurrence vs recurrence, P3: Non-recurrence, Pre-ablation vs post-ablation, P4: Recurrence, Pre-ablation vs post-ablation.

## Discussion

The findings of the present study showed that treatment of AF with RF ablation resulted in a statistically significant increase in gastroparesis symptoms independent of recurrence. Nevertheless, GCSI scores in patients with AF recurrence were found to be higher compared to patients without AF recurrence after ablation.

Functional gastrointestinal disorders such as gastroparesis have only a few objective clinical endpoints to use in clinical trials. The GCSI is a reliable and practical patient-based scale used for clinical trials to assess the severity of symptoms related to gastroparesis. Although not a definite threshold, the effect size for GCSI total scores is 0.67, indicating a medium effect size.<sup>8</sup> Higher GCSI scores indicate higher symptom severity.

Gastroparesis is defined as a delay in gastric emptying in the absence of demonstrated structural stenosis.<sup>9</sup> The periesophageal vagal plexus is positioned close to the posterior wall of the left atrium, rendering the esophagus highly sensitive to heat during ablation procedures. This heightened sensitivity can result in thermal damage, which is thought to contribute to gastrointestinal complications. However, the precise mechanism and true incidence of these complications remain elusive due to the subclinical nature of upper gastrointestinal hypo-motility symptoms in patients. Although scintigraphy is recommended as a standard method in diagnosis, depending on the various modality used, the incidence is in a very wide range.<sup>10</sup>

The lowest incidence was found to be 0.2% in the current studies conducted to date. However, only symptomatic patients were included in this study.<sup>11</sup> Furthermore, the patients were included in the questionnaire for symptom at the 3rd month and the diagnosis of gastroparesis was made by esophagogastroduodenoscopy. In another study in which similar rates were seen, it was found that the majority of the patients improved with conservative treatment in 40 days.<sup>12</sup> In contrast, in another study, all patients underwent esophageal manometry regardless of the presence of symptoms and gastroparesis was found in 48%.<sup>13</sup> Interestingly, gastrointestinal motility tests normalized in all patients at 6 months

follow-up. In another study, symptomatic gastroparesis developed after both cryoballoon ablation (10%) and RF ablation (2%).<sup>14</sup> In the current study, RF ablation was performed on all patients. The ablation strategy consisted of PVI with or without posterior wall isolation. Unfortunately, due to the relatively small number of patients, the relationship between RF ablation strategy and gastroparesis symptoms could not be evaluated.

Although upper gastrointestinal tract abnormalities after AF ablation have not been well addressed in the literature, according to functional studies, it is common and occurs in 74% of patients.<sup>15,16</sup> Most cases are detected as incidental. More importantly, it is not known which patients should be included in further investigation. The present study, on the other hand, showed an increase in hypomotility symptoms in all patients rather than giving a certain incidence rate. From this point of view, the results of the present study suggested that the GCSI scale may be a cost-saving screening test to select the appropriate patients for further investigation.

In different studies, it has been shown that the recovery period is between 1 month and 6 months after ablation.<sup>5,17</sup> And, as an inference of our study, we thought that all patients should be evaluated for gastroparesis-related symptoms after ablation. And, we believed that the recovery period can be reduced by using GCSI scale for rapid diagnosis and proper treatment.

The present study has several limitations. First, the study was conducted with a relatively small number of patients. Second, we did not use monitoring for esophageal temperature during PVI. Third, we did not perform diagnostic procedures like endoscopy, esophageal manometry or gastric emptying test. However, since this is a survey study, so, we feel that these diagnostic modalities fall outside the scope of this study.



## Conclusion

Gastroparesis associated symptoms are not uncommon after catheter ablation of AF. The GCSI scale may be useful index to predict gastroparesis due to AF ablation prior to further diagnostic procedures.

## Conflicts of Interest

The authors have no conflicts of interest to declare.

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