An alternative method for phrenic nerve monitoring during cryoballoon procedures

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BACKGROUND Cryoballoon ablation is associated with a consistent risk of phrenic nerve (PN) damage. Abdominal palpation associated with other strategies such as the diaphragmatic compound motor action potential (CMAP) has been shown to be an effective and reliable method for preventing this complication.

OBJECTIVE The purpose of this study was to evaluate the diagnostic performance of a new surface CMAP electrodes positioning.

METHODS A total of 150 patients underwent cryoballoon ablation. During the procedure, we placed the CMAP leads per the manufacturer's instructions and our alternative method, named NeedMAP, by placing electrocardiographic electrodes on the anterior axillary line. We simultaneously recorded the CMAP and the NeedMAP. CMAP monitoring with a 35% decrease cutoff for the diagnosis of nerve threatening was considered the gold standard. The NeedMAP decrease threshold also was set at 35%.

RESULTS A total of 438 cryoballoon applications were performed on the right pulmonary veins. Mean CMAP amplitude was 0.60 ± 0.33 mV compared to NeedMAP amplitude 0.85 ± 0.46 mV (P <.001). Among the 150 patients, 15 (10%) showed a nerve threat. In our population, the CMAP with regard to nerve damage had sensitivity of 38%, specificity 76%, negative predictive value (NPV) 89%, and positive predictive value (PPV) 19%. The NeedMAP showed sensitivity of 61%, specificity 86%, NPV 93%, and PPV 40%.

CONCLUSION The NeedMAP signal for PN monitoring during cryoballoon ablation seems to be a reliable method, shows good sensitivity and specificity, and can help clinicians in preventing PN damage.

KEYWORDS Atrial fibrillation; Phrenic nerve damage; Cryoballoon ablation; Compound motor action potential; Atrial fibrillation complications

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Introduction

Pulmonary vein isolation (PVI) is a well-established, effective, and relatively safe method for the treatment of atrial fibrillation (AF).[1,2] Cryoballoon (CB) ablation is an alternative to the well-established radiofrequency PVI, and it has demonstrated similar effectiveness as well as safety.[3] However, it has been associated with considerable risk of transient or permanent right phrenic nerve (PN) palsy during right PVI (nearly 4% in large trials, with almost 54% recovery by the end of the procedure; 97% recovery in 12 months, less than 1% showed symptomatic and permanent PN injury after 1 year from the procedure).[4] The PN provides the only motor output to the diaphragm. The right PN is in close proximity to the right pulmonary veins (PVs) as it approaches the superior cavo–atrial junction before reaching the right hemidiaphragm.[5] Although abdominal palpitations and imaging techniques such as chest radiography and/or intracardiac echocardiographic visualization of diaphragmatic motion are routinely used to monitor PN integrity during a cryoablation procedure, the diaphragmatic compound motor action potential (CMAP) has been proven to be equal effective in monitoring and preventing PN injury and is widely used.[6,7] In our hospital, along with the CMAP we have been using an alternative method, which we named NeedMAP: NEgrar (our city) Enhanced Diaphragmatic Motor Action Potential, for monitoring the PN during AF cryoablation. The purpose of this study was to evaluate the diagnostic performance of our method compared to CMAP.

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KEY FINDINGS

- Cryoballoon ablation is associated with a consistent risk of phrenic nerve damage.
- Currently, only the diaphragmatic compound motor action potential (CMAP) has been shown to be effective in preventing this complication.
- By placing electrocardiographic electrodes for CMAP recording on the anterior axillary line, the mean amplitudes are significantly higher, making the signals more readable than standard position CMAP recording.
- This alternative position showed higher sensitivity and specificity than standard CMAP with regard to phrenic nerve damage during cryoballoon ablation.

Methods

We conducted a retrospective, single-center, comparative, observational study. We enrolled 150 consecutive patients with paroxysmal AF who underwent only PVI isolation via CB ablation in our hospital from 2021 to 2023. AF ablation was offered according to current international guidelines. All patients provided written informed consent. The study was approved by the Institutional Ethic Board. This study adhered to the ethical principles outlined in the Declaration of Helsinki.

CB ablation procedure

Cardiac computed tomography was performed the day before the procedure to assess the PV anatomy and possible left atrial appendage thrombi. The ablations were performed with patients on uninterrupted anticoagulation and under general anesthesia to prevent patient movement, pain, and discomfort. Intraprocedural transesophageal echocardiography confirmed the absence of left atrial appendage thrombi and guided the transseptal puncture. A 12F steerable sheath (FlexCath, CryoCath, Medtronic Inc., Minneapolis, MN), 28-mm CB (Arctic Front Advance, Medtronic Inc.), and inner circular catheter (Achieve mapping catheter, Medtronic Inc.) were used for PVI in all patients. All PVs were individually isolated by cryoapplication, and the endpoint was demonstrated by achieving entrance and exit block. During cryoapplications on the right PVs, PN signals were monitored under constant PN stimulation, and ablation was stopped if a reduction in CMAP amplitude and/or impaired diaphragmatic contraction (assessed by either abdominal palpation and/or impairment of diaphragm movements on radiography) were observed.[6–9]

PN monitoring

A quadripolar Josephson Curve catheter (Response, Abbott, Plymouth, MN) was positioned in the superior vena cava, usually at the junction between the right innominate/brachiocephalic vein and the superior vena cava until stable PN capture was established, with the aim of obtaining CMAP amplitude >0.3 mV. We paced the right PN usually at 60 stimulations per minute at twice the capture threshold (bipolar stimulation between proximal and distal electrodes with maximal output of 5 V at 4 ms). Diaphragmatic contraction was confirmed by abdominal palpation and radiographic assessment of diaphragm movements.

CMAP monitoring was performed following the instructions of the manufacturer (Medtronic Inc.). The electrocardiographic (ECG) configuration as well as the methodology of CMAP recording have been described elsewhere.[10–12] In brief, a modified ECG lead I was used by placing a standard surface right arm ECG electrode 5 cm above the xiphoid and a left arm ECG electrode 16 cm along the right costal margin (Figure 1). CMAP amplitude was measured from peak to peak with each PN capture. A 35% drop in CMAP amplitude has been shown in studies to be the threshold for prevention of PN injury. During the procedure, the operators or the investigators at the recording system console were visually checking the signals. In case of CMAP amplitude drop below the threshold, the cryoapplication was immediately terminated. If a PN threat was observed, cryoapplication was stopped immediately using a forced deflation maneuver. In case of PN threats, pacing was prolonged by 2 minutes to observe CMAP recovery. Complete recovery was defined as CMAP amplitude >90% compared with baseline, 2 minutes after cryoapplication was interrupted.

The NeedMAP was simultaneously obtained and recorded alongside the CMAP, and served as a complementary measurement. The NeedMAP was obtained by placing 2 additional standard surface ECG electrodes, the first at the anterior axillary line 20 cm horizontally from the modified right arm CMAP electrode and the second on the anterior axillary line 20 cm caudally from the first NeedMAP surface electrode (Figure 1). These 2 electrodes, instead of being connected to the 12-lead ECG port, were connected to the 40-channel intracardiac electrogram (EGM) junction box of the recording system using a band-pass filtered between 0.5 and 50 Hz. The signals obtained were amplified 16-fold (same setting as the CMAP). NeedMap and CMAP amplitudes were continuously monitored during CB ablation, and the same 35% amplitude drop threshold was used to avoid inhomogeneities in our observations. Diaphragmatic contraction was confirmed by abdominal palpation and radiographic assessment of diaphragm movements.

After the procedures, postprocessing CMAP and NeedMAP amplitude measurements were performed using the LABSystem PRO workstation (Bard, Boston Scientific, Marlborough, MA) by 2 senior electrophysiologists.

Statistical analysis

Continuous variables are given as mean ± SD or median [interquartile range), and categorical variables are given as percentage. Receiver operating characteristic curves, plotting sensitivity against 1 – specificity, were also used to assess the performance of the 2 PN mapping methods (NeedMAP [Negrar method] and CMAP [standard method]). Area under the receiver operating characteristic curve (AUC) with 95%

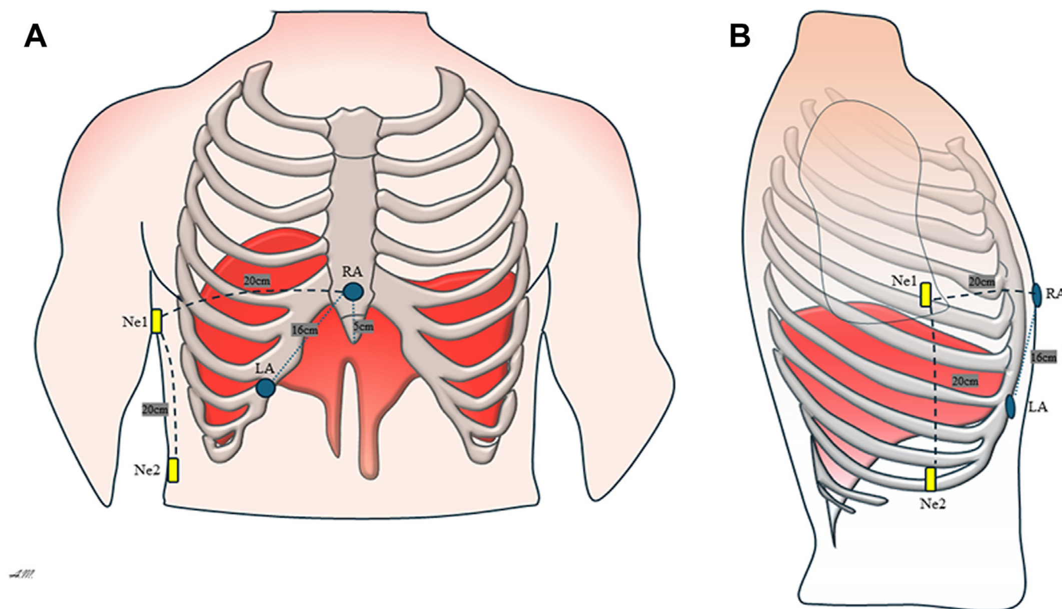


Figure 1 **A:** Front view of the chest (ribs, sternum in *gray;* diaphragm underneath in *red*) with the positions of the CMAP and NeedMAP leads. CMAP with RA *(blue dot)* = right arm ECG lead 5 cm above the xiphoid; LA *(blue dot)* = left arm ECG lead 16 cm from RA along the costal margin. NeedMAP leads (Ne1, Ne2) are indicated by the *yellow boxes.* Ne1 is located 20 cm laterally from the RA along the anterior axillary lane; Ne2 is located 20 cm below Ne1 following the anterior axillary lane. **B:** Lateral view of the chest with the same leads. CMAP = diaphragmatic compound motor action potential; NeedMAP = NEgrar (our city) Enhanced Diaphragmatic Motor Action Potential.

confidence interval (CI) was calculated under nonparametric (distribution free) assumption. For the classic cutoff (–35%), sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were reported for the 3 PN mapping methods. The DeLong method was used to compare the AUCs of the 3 PN mapping methods.

All statistical tests were 2-sided, and P <.05 was considered significant. R Version 4.4.0 (R Core Team 2024, R Foundation for Statistical Computing, Vienna, Austria) was used for all statistical analyses using pROC and cutpointr.

Results

Between January 2021 to December 2023, 150 patients underwent CB AF ablation. A total of 838 CB applications were performed (mean 5.9 applications for each patient), with 438 applications on the right PVs (mean 2.9 applications each). Patient and procedural characteristics are summarized in Table 1.

Mean baseline values of CMAP amplitudes were 0.60 ± 0.33 mV, whereas NeedMAP amplitudes were 0.85 ± 0.46 mV (P <.001).

Aiming to evaluate whether the quality and amplitude of the signals could be influenced by the connection ports (12-lead ECG port vs EGM junction box), we used another modified CMAP lead I that was connected, like the NeedMAP, to the 40-channel EGM junction box, using the same bandpass filter and amplification, instead of being connected to the 12-lead ECG port. Although the study was not designed for this, no statistically significant differences were found when comparing the standard CMAP amplitudes connected to the 12-lead ECG port vs the modified CMAP with the leads connected to the EGM junction box of the recording system (0.60 ± 0.33 mV vs 0.66 ± 0.50 mV respectively, P = .26).

Comparing CMAP and NeedMAP signals with regard to body mass index (BMI), NeedMAP performed better than CMAP for patients with BMI >25 (mean 0.92 ± 0.35 mV vs 0.6 mV ± 0.32 respectively, P = .0003). Similarly, for patients with BMI <25, the NeedMap performed better than CMAP (mean 0.74 ± 0.27 mV vs 0.51 ± 0.29 mV, P = .02).

Among the 150 patients, 15 (10%) exhibited evidence of PN compromise as defined by drop of CMAP amplitude to <35% threshold. It was more frequent at the right superior PV than the right inferior PV (12 vs 3, respectively, P = .017). For these patients with PN damage, CMAP amplitude reduction was 39.9% ± 20% vs NeedMAP 58.7% ± 12% (P = .005). Cryoablation temperatures when nerve injury

Table 1 Patient (N = 150) and procedural characteristics

Age, y	62.7 ± 9.1
Male sex	116 (77)
BMI, kg/m^2	26.6 ± 4.4
Paroxysmal/persistent AF, %	71/29
HTN/diabetes/OSA, %	48/4.7/21.6
Antiarrhythmic treatment	56 (37)
Ischemic heart disease	7 (4)
CHADS-VASc score	1.9 ± 1.4
LVEF, %	61.8 ± 8.7
LA volume indexed for BSA, mL/m^2	38.7 ± 10.6
Total procedural time, min	70.2 ± 21.9
Fluoroscopy time, min	16.5 ± 12.9
Total no. of applications/right-sided	898/438

Values are given as mean ± SD or no. (%), unless otherwise indicated.

AF = atrial fibrillation; BMI = body mass index; BSA = body surface area; HTN = arterial hypertension; LA = left atrium; LVEF = left ventricular ejection fraction; OSA = obstructive sleep apnea.

Table 2 Patient, timing, and CMAP/NeedMAP characteristics of patients in whom phrenic nerve damage was recorded

Pt. no (sex)	Age, y	Vein	Temperature, °C	CMAP* (mV)	NeedMAP* (mV)	Sec PND	Sec 35% (ΔSec)	Recover
1 (M)	53	RS	–52	0.47/0.42 (10.6%)	0.66/0.37 (43.9%)	115	ND/112 (ND)	<2 min
2 (M)	74	RS	–53	0.43/0.30 (30.2%)	0.78/0.40 (48.7%)	125	ND/123 (ND)	<2 min
3 (M)	65	RS	–55	0.99/0.50 (49.4%)	1.49/0.44 (70.4%)	126	125/121 (4)	<2 min
4 (M)	59	RI	–58	0.49/0.28 (42.8%)	1.24/0.76 (38.7%)	114	113/110 (3)	<2 min
5 (M)	47	RS	–54	0.32/0.27 (12.5%)	0.83/0.33 (60.2%)	136	ND/134 (ND)	<24 h
6 (M)	60	RS	–51	0.44/0.34 (22.7%)	0.57/0.25 (56.1%)	124	ND/123 (ND)	<2 min
7 (M)	60	RS	–50	0.61/0.53 (13.1%)	0.78/0.45 (42.3%)	125	ND/122 (ND)	<2 min
8 (M)	55	RS	–52	0.60/0.43 (28.3%)	0.86/0.30 (65.1%)	143	ND/145 (ND)	No
9 (M)	59	RI	–54	0.80/0.49 (38.7%)	1.36/0.70 (48.5%)	146	145/141 (4)	<2 min
10 (M)	50	RS	–56	0.42/0.27 (35.7%)	1.16/0.48 (58.6%)	156	156/153 (3)	<24 h
11 (M)	66	RS	–55	0.32/0.11 (65.6%)	0.85/0.22 (74.1%)	126	124/121 (3)	<2 min
12 (M)	46	RI	–53	0.39/0.11 (71.8%)	0.55/0.15 (72.7%)	103	101/99 (2)	<2 min
13 (F)	76	RS	–54	0.59/0.19 (67.7%)	0.69/0.17 (75.3%)	120	119/116 (3)	<24 h
14 (M)	49	RS	–57	0.36/0.14 (61.1%)	0.54/0.23 (57.4%)	135	134/132 (2)	<2 min
15 (M)	51	RI	–54	0.47/0.24 (48.9%)	0.66/0.21 (68.1%)	100	98/96 (2)	<2 min
Mean± SD	58	12/3	54	0.51/0.30 (39.9%)	0.87/0.36 (58.7%)	126.2	123.9/123.2 (2.89)	
	9.24		2.17	0.18/0.14 (20.6)	0.3/0.18 (12.2)	15.3	19.1/15.9 (0.78)	

F = female; M = male; RI = right inferior; RS = right superior; Temperature = temperature at which phrenic nerve damage (PND) occurred; Sec 35% (ΔSec) = seconds after cryoapplication started when diaphragmatic compound motor action potential (CMAP) and NEgrar (our city) Enhanced Diaphragmatic Motor Action Potential (NeedMAP) reached the threshold of 35% (difference in seconds); Sec PND = seconds after the beginning of cryoapplication when PND occurred; ND = no data because the threshold was not achieved; Recover = if and when PND recovered (within 2 minutes, 24 hours, or not at all [only in pt. 8]); Vein = vein where phrenic nerve damage (PND) occurred during cryoapplication.

*CMAP and NeedMAP values with basal/after cryoapplication (amplitude percentage reduction).

occurred were –54°C ± 2.17°C. Complete recovery of CMAP amplitude was observed in 11 of 15 cases, within 2 minutes. Chest radiograph the day after showed no PN palsy in 14 patients. One patient suffered permanent PN palsy.

The NeedMAP reached the 35% amplitude reduction consistently earlier than CMAP (mean 2.89 ± 0.78 seconds, P = .59). In 6 of 15 patients, we recorded PN impairment without reaching 35% CMAP amplitude reduction. Table 2 summarizes the characteristics of these 15 patients who showed PN injury/threat during the CB procedures.

NeedMAP diagnostic performance is summarized in Figure 2B. With regard to PN injury, in our population CMAP had sensitivity of 38%, specificity 76%, accuracy 71% (AUC 0.710, 95% CI 0.56–0.85), NPV 89%, and PPV 19%. NeedMAP showed sensitivity of 61%, specificity 86%, accuracy 83% (AUC 0.806, 95% CI 0.68–0.92), NPV 93%, and PPV 40%.

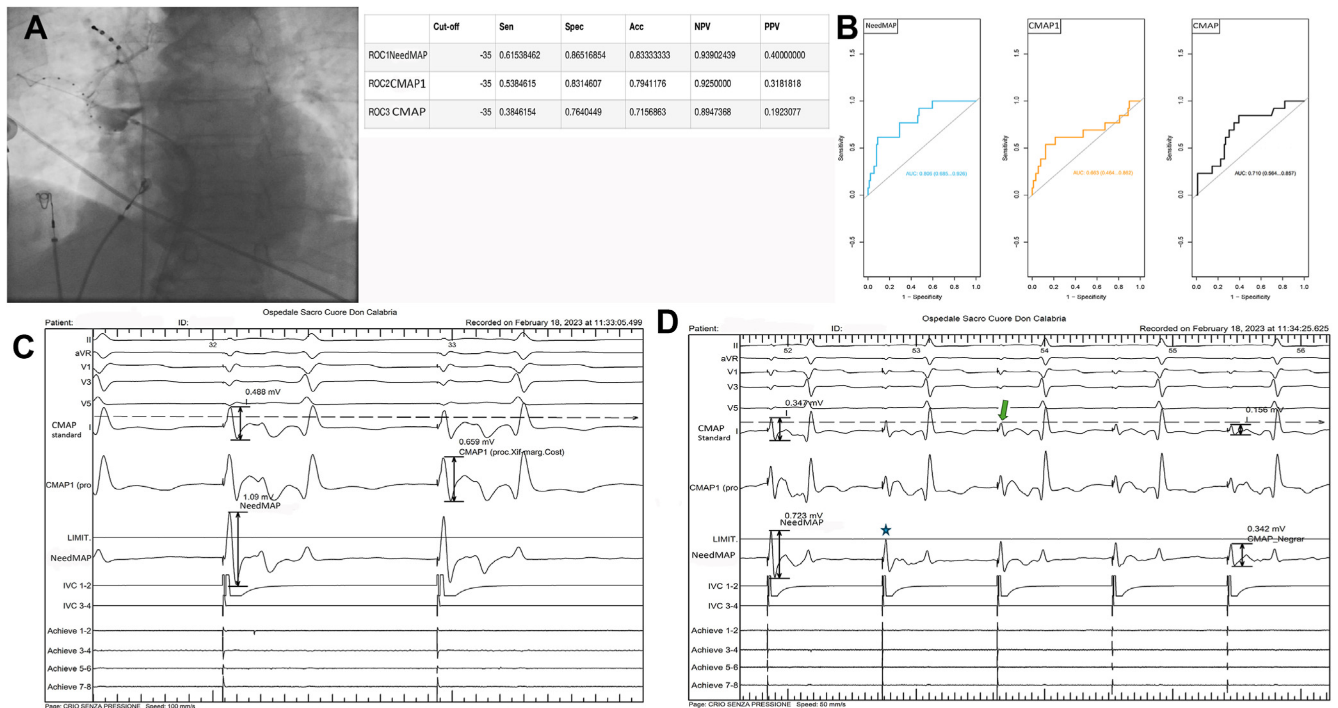
Finally, 111 of 150 patients (74%) with no PN injury demonstrated a progressive decrease in CMAP and NeedMAP amplitudes from the beginning of the applications until the end, with mean reductions of 16.9% ± 6.6% and 13.6 ± 4.6%, respectively (P = .006), consistent with the known diaphragmatic fatigue phenomenon.

Discussion

CB is an effective and relatively safe and quick method for AF ablation. However, PN injury is a well known and not uncommon risk of this procedure. Since its introduction into common clinical practice, many studies have attempted to determine the best way to prevent and avoid PN damage. The introduction of CMAP signals as an adjunct to abdominal palpation and imaging (chest radiography and/or intracardiac echocardiography) has provided enormous support to clinicians performing AF ablation using CB. However, PN damage still occurs at a relatively high percentage (albeit transient in almost all cases) compared to other AF ablation technique, the latest being pulsed field ablation.

In our study, by placing the ECG electrodes in a different position compared to the "standard" ones of the CMAP and connecting them to the EGM junction box of the recording system instead of the ECG port and keeping the same band-pass filter (0.5–50 Hz) and amplitude (16-fold), we obtained higher voltage signals that were more reliable and better able to be interpreted. By placing the leads on the anterior axillary line, 20 cm from each other, more of the diaphragm dome contraction is recorded, generating a higher and better-quality signal. Furthermore, these lead positions and the signals generated are not particularly influenced by body fat and BMI, maintaining good voltage average and quality. These characteristics do not seem to be influenced by the port where the leads are connected (12-ECG vs EGM junction box), as demonstrated by the analysis of standard vs modified CMAP.

Moreover, this study found that NeedMAP has sensitivity of 61%, specificity 86%, and accuracy 83% (AUC of 0.80). Statistically, for a test to be useful, sensitivity plus specificity should be at least 1.5 (ie, 1 for useless and 2 perfect).[13] In our study, NeedMAP performed at 1.47 (0.61 + 0.86), whereas the sum of sensitivity + specificity for CMAP was 1.14 (0.38 + 0.76), in the same population, at the same time. It is known that low specificity could lead to inappropriate interruption of cryoenergy, while PN is not threatened. Likewise, low sensitivity, with possible false negative, can increase the risk of PN injury. Furthermore, these combinations could lead to increases in procedural and fluoroscopy times and amount of contrast used.



	Cut-off	Sen	Spec	Acc	NPV	PPV
ROC1NeedMAP	-35	0.61538462	0.86516854	0.83333333	0.93902439	0.40000000
ROC2CMAP1	-35	0.5384615	0.8314607	0.7941176	0.9250000	0.3181818
ROC3 CMAP	-35	0.3846154	0.7640449	0.7156863	0.8947368	0.1923077

Figure 2 **A:** Quadripolar catheter placed in the superior vena cava at the junction with the innominate/brachiocephalic branch. Cryoballoon inflated, contrast within the right superior pulmonary vein, and the Achieve mapping catheter can be seen. **B:** Statistical performance of the phrenic nerve mapping methods NeedMAP (Negrar method), CMAP (standard method), and CMAP1 (CMAP leads connected to the electrogram junction box of the recording system) with receiver operating characteristic (ROC) curves and area under the receiver operating characteristic curves (AUC), showing specificity (Spec), sensitivity (Sen), accuracy (Acc), negative predictive value (NPV), and positive predictive value (PPV). **C, D:** Electrograms during cryoablation showing the baseline values of the monitoring methods used (100 mm/s speed) **(C)** and a case of phrenic nerve damage, clearly showing the abrupt amplitude reduction of the NeedMAP *(blue star)* below the 35% threshold (*continuous horizontal line* for NeedMAP and *dotted line* for CMAP), less evident with standard CMAP (*green arrow,* when CMAP reached its 35% reduction, almost 1 second after NeedMAP) **(D).** IVC = quadripolar catheter pacing the phrenic nerve. Abbreviations as in Figure 1.

Therefore, NeedMAP seems to be a reliable method and likely not inferior to CMAP for PN monitoring during CB ablation. Certainly, larger-scale comparative studies would be necessary to assess properly the noninferiority.

In the patient with permanent PN palsy, CMAP showed a reduction of 28.3% (not yet below the threshold of 35%), whereas NeedMAP already was 65%. In this case, NeedMAP reached the threshold of 35%, 2.8 seconds earlier than CMAP. However, this finding (ie, earlier achievement of the threshold by NeedMAP compared to CMAP) was not statistically significant (P = .59) for the whole study, probably because of the small sample. However, the percentage of amplitude reduction between CMAP and NeedMAP did show a statistically significant value (P = .005), demonstrating a more readable and sensible monitoring method.

The threshold of 30% or 35% is mostly arbitrary because it has not been assessed by randomized controlled trials. These thresholds were extrapolated from different studies. Lakhani et al[11] demonstrated that the threshold of 35% was able to discriminate CB application with and without PN injury (respectively higher vs lower than 35% of reduction of CMAP signals). Franceschi et al[10] described a different method of recording phrenic CMAP amplitude during CB ablation by advancing a quadripolar catheter in the right hepatic vein during PN pacing. In their study, ablation was discontinued if the observed CMAP amplitude decreased by ≥30% from baseline.[7–12] There were no reported cases of PN damage, including the patients in whom ablation was discontinued early because of a decrease in CMAP amplitude. A synthesis of published data suggests that ceasing CB ablation immediately on reduction of CMAP amplitude of 30%–35% can successfully prevent long-standing and persistent PN damage during right-sided PV cryoablation. Recently, Schemoul et al[14] described the diagnostic performance of a different PN monitoring tool integrated in the Smartfreeze console (Boston Scientific, St. Paul, MN), showing a better outcome and performance using the CMAP as gold standard instead of the alternative method.

It has been suggested that the PN should be paced at twice the capture threshold during CB ablation. A high current strength potentially can overcome early nerve injury and conceal incipient damage to the nerve.[15] Moreover, catheter stability and reliable capture of the PN are essential because sudden loss of capture, due to catheter movements, may mimic PN damage and cause unnecessary cessation of ablation. The PN should be paced at cycle lengths ranging from 1500 to 1000 ms. A slower pacing rate can delay the detection of PN palsy, and a rapid pacing rate can prematurely fatigue the diaphragm.[16,17] Nevertheless, despite a pacing rate of 60b pm (1000 ms) and pacing output of maximum 5 V at 4 ms, we found a consistent rate of CMAP and NeedMAP amplitude reduction that can be explained by the muscular

fatigue phenomenon. Muscular fatigue represents an important limitation to PN monitoring with diaphragmatic movements and can make the threshold of 35% not always completely reliable, and even more so for the 30% threshold.

It is imperative that paralytics not to be administered during ablation. If they were administered during the induction of general anesthesia, sufficient time should be allowed for the paralytic effect to reverse before ablation.

Study limitations

This was a monocentric, retrospective study that are limitations on their own. To conclusively evaluate the safety and efficacy of the PN monitoring method we are proposing in comparison to the standard CMAP, larger-scale comparative studies with formal hypotheses and statistical power calculations would be required.

Conclusion

PN monitoring during CB ablation with the NeedMAP signal seems to be a safe and reliable method, showing good sensitivity, specificity, and accuracy, and can help clinician in preventing PN injury. It seems to be not inferior to the CMAP signal, which is used as the gold standard. However, further large-scale studies are needed to confirm its efficacy and safety.

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Patient Consent: All patients provided written informed consent.

Ethics Statement: The study was approved by the Institutional Ethic Board. This study adhered to the ethical principles outlined in the Declaration of Helsinki.

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