

Original Article

Comparison of Short- and Long-term Outcomes of AF Patients Treated With Cryoballoon Ablation or Radiofrequency Ablation in a 2-Year Hospital Registry

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ABSTRACT

Background: Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia. Rhythm control is a treatment option. Ablation is done via 2 different methods: radiofrequency (RF) ablation and cryoballoon ablation. An evaluation of the outcome of these methods in a tertiary center is necessary.

Methods: This historical cohort study recruited 299 patients undergoing ablation. RF was performed on 150 patients, while 149 underwent cryoballoon ablation. Age, sex, risk factors (diabetes mellitus, hypertension, and renal failure), symptoms (palpitations, dyspnea, bradycardia, dizziness, and chest pain), echocardiography data, and complications were extracted from documents. Baseline characteristics and outcomes were compared between the 2 groups.

Results: All baseline characteristics were comparable between the 2 groups, except age ($P=0.029$), renal failure ($P=0.018$), and the left ventricular ejection fraction ($P=0.011$), which were higher in the cryoballoon group. The overall complication rate was higher in the RF group ($P=0.021$), but the 2 groups were comparable concerning each complication. Recurrence within less than 1 month was higher in the cryoballoon group ($P=0.002$).

Conclusions: Both RF and cryoballoon methods have their advantages and disadvantages. A historical cohort study to compare the outcomes between these 2 methods is not the proper choice in that it fails to determine which procedure confers a better outcome. A prospective survey seems more suitable for this evaluation. (*Iranian Heart Journal 2022; 23(3): 59-63*)

KEYWORDS: Atrial fibrillation, Radiofrequency ablation, Cryoballoon ablation, Complications

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Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia.¹ Not only does AF increase mortality, cause many disabilities, and impair the quality of life, but also it is difficult to treat.²⁻⁴ Emerging evidence implicates triggered activity arising in the pulmonary veins in initiating and maintaining paroxysmal AF.^{5,6} Antiarrhythmic drugs lack efficacy when chosen for a rhythm control strategy in AF and have been less effective than catheter ablation.^{7,8} Various techniques and different ablation strategies have been developed, with radiofrequency (RF) currently being the most widespread energy source. Cryothermal energy is an alternative energy source developed to overcome some of the disadvantages of RF ablation, such as tissue disruption by excess heating and inhomogeneous lesion generation.⁹

METHODS

Study Population

This historical cohort study was conducted on patients with persistent and paroxysmal AF subjected to RF or cryoballoon ablation at our institution between March 2016 and March 2019. All data were retrieved from recorded documents. The enrolled population was composed of patients diagnosed with AF via 12-lead electrocardiography (ECG) or Holter monitoring and chosen to be treated with ablation via either RF ablation or cryoballoon ablation. Follow-up data were gathered from the studied patients when they referred to the clinic at scheduled times or after they experienced the onset of AF symptoms such as irregular palpitations.

Ablation

RF ablation was performed with the NAVX Precision device (Abbott Laboratories, Abbott Park, Illinois, USA), and the cryoballoon ablation was performed with the Medtronic device (Medtronic Parkway, Minneapolis, MN Device, USA).

Statistical Analysis

The χ^2 test was used to compare nominal variables. The Student *t* test, one-way ANOVA, or their nonparametric equivalents (the Mann–Whitney or Kruskal–Wallis test) were applied to compare continuous variables. Ordinal regression tests were drawn upon for the nonparametric comparisons of outcomes, risk factors, and symptoms. The Levene test was used to check the homogeneity of variance. Results with a *P* value of less than 0.05 were regarded as significant. All the statistical analyses were performed using the Statistical Package for Social Sciences version 26 (SPSS Inc, Chicago, IL, USA).

RESULTS

Of the 299 patients undergoing ablation in this study, 150 were treated with RF ablation and 149 with cryoballoon ablation. All demographic and baseline characteristics were comparable between the 2 groups. The only exceptions were age, the left ventricular ejection fraction (LVEF), and renal failure. The cryoballoon group was significantly older ($P=0.029$). The baseline LVEF was significantly higher in the cryoballoon group ($P=0.011$), which is a shortcoming in our study because of its lack of randomization and historical nature. Women comprised 47.5% of the study population. Concerning risk factors, diabetes mellitus was reported in 13.7% of the patients, hypertension in 36.8%, and renal failure in 3%. The prevalence of renal failure was significantly different between the 2 groups ($P=0.018$). Regarding symptoms related to AF, palpitations were reported in 49.8% of the studied patients, dyspnea in 9.7%, bradycardia in 1.7%, chest pain in 5.7%, and dizziness in 4.7%. The symptoms were all comparable between the 2 study groups.

The study population's baseline characteristics are presented in Table 1.

The mean left atrial diameter was 3.69 ± 1.38 cm, and the mean left atrial area was

21.26±5.26 mm². Left atrial dilation (>40 mm or >20 mm²) was present in 28.1% of the patients based on the left atrial diameter and 49.2% based on the left atrial area. Preserved LVEF (>50%) was reported in 50.5% of the patients.

No significant relationships were found between reduced LVEF and any complications (overall complication $P=0.807$). Phrenic nerve palsy, a known

complication of the cryoballoon method, occurred more commonly in the cryoballoon group ($P=0.001$).

The mean recurrence time was 9.04±8.2 months, with no significant difference between the 2 groups ($P=0.154$). Nonetheless, the recurrence time was significantly different in less than 1-month periods and was more common in the cryoballoon group ($P=0.002$) (Table 2).

Table 1: Baseline sample characteristics

| | All | Radiofrequency (n=150) | Cryoballoon (n=149) | P value |
|--|-------------|------------------------|---------------------|--------------|
| Q, %, (n) | 47.5(142) | 50.7(76) | 44.3(66) | 0.270 |
| Age(y) | 55.59±12.66 | 57.19±12.26 | 53.99±12.89 | 0.029 |
| Left atrial diameter (cm) | 3.72±1.07 | 3.69±1.38 | 3.75±0.61 | 0.634 |
| Left atrial enlargement by diameter % (n) | 28.1(84) | 25.3(38) | 30.9(46) | 0.287 |
| Left atrial area (mm ²) | 21.26±5.26 | 21.47±4.50 | 21.05±5.94 | 0.492 |
| Left atrial enlargement by area % (n) | 49.2(147) | 50.7(76) | 47.7(71) | 0.602 |
| Ejection fraction % | 48.94±9.17 | 47.60±10.51 | 50.30±7.38 | 0.011 |
| Reduced left ventricular ejection fraction % (n) | 49.5(148) | 51.3(77) | 47.7(71) | 0.524 |
| Recurrence time (mon) | 9.04±8.20 | 9.72±7.21 | 8.36±9.06 | 0.154 |
| Complications % (n) | 32.4(97) | 38.7(58) | 26.2(39) | 0.021 |
| Phrenic nerve palsy % (n) | 18.7(56) | 10.7(16) | 26.8(40) | 0.001 |
| Diabetes mellitus % (n) | 13.7(41) | 14 (21) | 13.4(20) | 0.885 |
| Hypertension % (n) | 36.8(110) | 39.3(59) | 34.2(51) | 0.360 |
| Renal failure % (n) | 3(9) | 5.3(8) | 0.7(1) | 0.018 |
| Palpitation % (n) | 49.8(149) | 54.7(82) | 45(67) | 0.093 |
| Dyspnea % (n) | 9.7(29) | 12(18) | 7.4(11) | 0.612 |
| Bradycardia % (n) | 1.7(5) | 2.7(4) | 0.7(1) | 0.195 |
| Dizziness % (n) | 4.7(14) | 6(9) | 3.4(5) | 0.279 |
| Chest pain % (n) | 5.7(17) | 4.7(7) | 6.7(10) | 0.445 |
| Paroxysmal atrial fibrillation % (n) | 22.4(67) | 16(24) | 28.9(43) | 0.008 |
| Persistent atrial fibrillation % (n) | 77.6(232) | 84(126) | 71.1(106) | |

Table 2: Complications and recurrence rates, as well as comparison between the radiofrequency and cryoballoon groups

| | All | Radiofrequency | Cryoballoon | P value |
|-----------------------------------|-----------|----------------|-------------|--------------|
| Pericardial effusion % (n) | 3(9) | 4(6) | 2(3) | 0.748 |
| Bleeding % (n) | 17.4(52) | 20(30) | 14.8(22) | 0.088 |
| Vascular % (n) | 12(36) | 14.7(22) | 9.4(14) | 0.759 |
| Recurrence within 1 month % (n) | 11.7(35) | 9.3(14) | 14.1(21) | 0.002 |
| Recurrence within 6 months % (n) | 36.1(108) | 28(42) | 44.3(66) | 0.187 |
| Recurrence within 12 months % (n) | 31.1(93) | 40(60) | 22.1(33) | 0.057 |
| Recurrence >12 months % (n) | 21.1(63) | 22.7(34) | 19.5(29) | 0.188 |

DISCUSSION

We observed a significant difference in age between our RF and cryoballoon groups in that the mean age was higher in the RF group. The coexistence of other arrhythmias can explain this finding with AF in older patients. With the RF procedure, the ablation of other arrhythmias is possible, which is not achievable in the cryoballoon method. Notably, the nature of our study precluded matching in terms of this parameter. Our results also revealed a significant difference in the mean LVEF between the 2 procedure groups, with the variable being higher in the cryoballoon group ($P=0.011$). This finding can be explained by the historical nature of our study, and a prospective investigation can overcome this mismatch between the 2 groups.

The overall complication rate was higher in the RF group than in the cryoballoon group, and the difference was significant ($P=0.021$). The fact that the mean age was significantly higher in the RF group was a confounding factor leading to this result; nevertheless, each complication considered individually was not statistically different between the 2 groups. This finding is not consistent with previous studies¹⁰ and is, thus, a shortcoming of our study. Achieving reliable data requires a propensity-matched investigation.

Phrenic nerve palsy was statistically significantly more in the cryoballoon group ($P=0.001$). We expected this result since phrenic nerve palsy is a known complication of this procedure.¹¹

The cryoballoon procedure was used more often in patients with paroxysmal AF, with the difference between the 2 methods constituting statistical significance ($P=0.008$). This finding is due to the nature of paroxysmal AF, which is more amenable to ablation with the cryoballoon procedure because the origin of most paroxysmal AF cases is the pulmonary vein.¹²

Limitations

The present study has several limitations that should be highlighted. This investigation was a historical cohort study, neither randomized nor controlled, and baseline characteristics were not all comparable. Thus, some of our findings might have been affected by the 2 non-matched groups. In our country, cryoballoon ablation is more expensive than the RF method, which might lead to a different selection of patients and better compliance with drugs among wealthier patients.

CONCLUSIONS

RF ablation and cryoballoon ablation both have their advantages and disadvantages. Some of the findings of the current investigation are not consistent with other studies because our 2 groups were not matched. A randomized clinical trial seems a more preferable option to a historical cohort study to reveal more reliable findings.

Conflict of Interest

The authors do not have any conflicts of interest to declare.

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