Nurse-led care after ablation of atrial fibrillation : a randomised controlled trial

Nurse-led care after ablation of atrial fibrillation: a Randomised Controlled Trial

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Abstract

Background and aims: The added value of advanced practitioner nurse (APN) care after ablation of atrial fibrillation (AF) is unknown. The present study investigates the impact of APN-led care on AF recurrence, patient knowledge, lifestyle, and patient satisfaction.

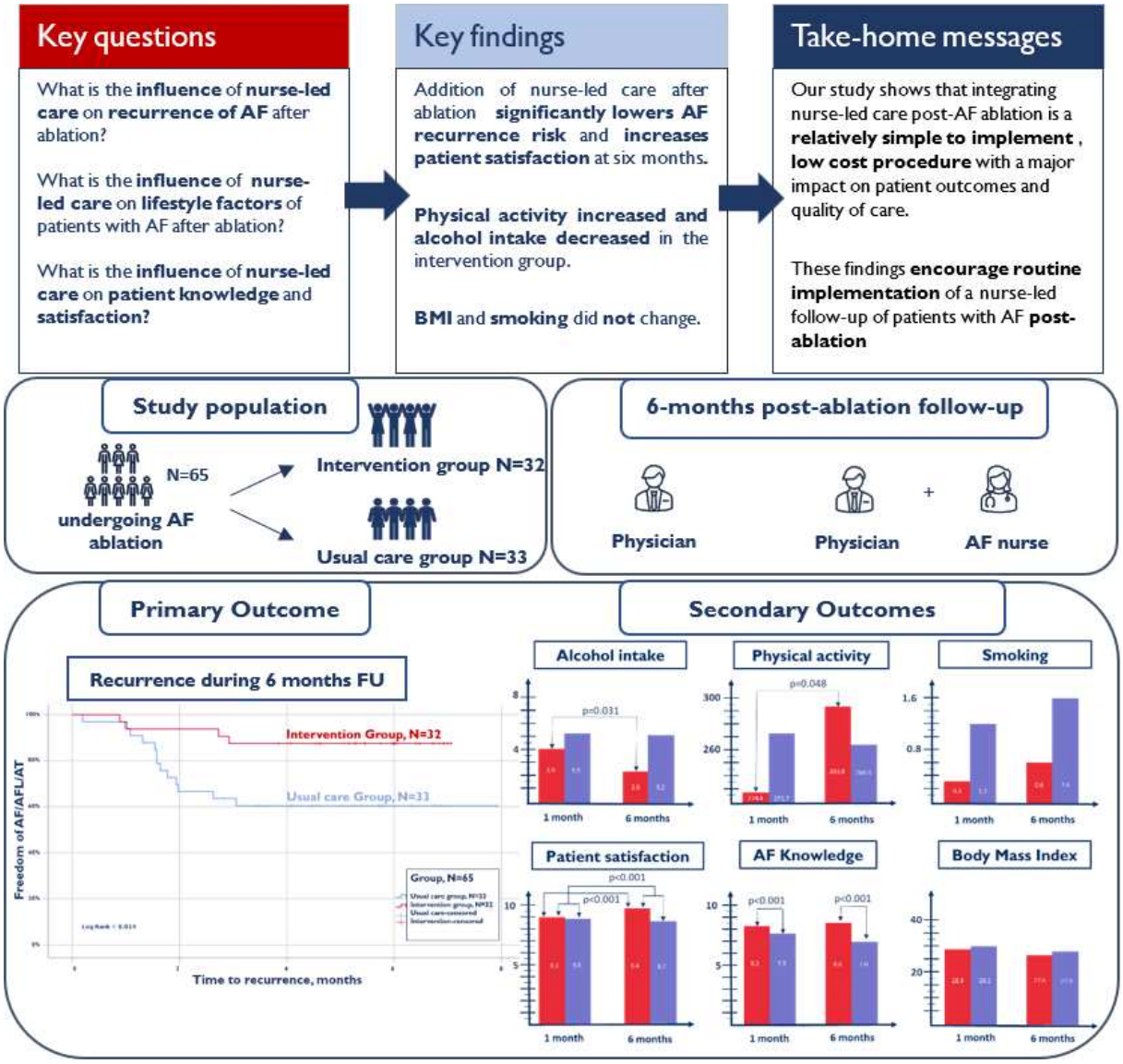
Methods: 65 patients undergoing AF ablation were prospectively randomised to usual care (N=33) or intervention (N=32) group. In addition to usual care, the intervention consisted of an educational session, three consultations spread over six months and telephone accessibility coordinated by the APN. Primary outcome was the AF recurrence rate at 6-month follow-up. Secondary outcomes were lifestyle factors (alcohol intake, exercise, BMI, smoking), patient satisfaction and AF knowledge measured at 1 and 6 months between groups and within each group.

Results: Study demographics at 1 month were similar, except AF knowledge was higher in the intervention group (8.6 versus 7, p=0.001).

At 6 months, AF recurrence was significantly lower in the intervention group (13.5% vs 39.4%, p=0.014). Between groups, patient satisfaction and AF knowledge were significantly higher in the intervention group, respectively 9.4 vs. 8.7 (p<0.001) and 8.6 vs 7.0 out of 10 (p<0.001). Within the intervention group, alcohol intake decreased from 3.9 to 2.6 units per week (p=0.031) and physical activity increased from 224.4±210.7 to 283.8±169.3 (p=0.048). No changes occurred within the usual care group. Assignment to the intervention group was the only protective factor for AF recurrence (Exp(B) 0.299, p=0.04) in multivariable-adjusted analysis.

Conclusion: Adding APN-led care after ablation of atrial fibrillation improves short-term clinical outcome, patient satisfaction and physical activity and decreases alcohol intake.

Graphical abstract



Lay summary

The present study investigates the added value of advanced practitioner nurse (APN)-led care consisting of an educational session, three consultations spread over six months and telephone accessibility coordinated by the APN in patients after ablation of atrial fibrillation (AF).

Main findings are:

- The addition of nurse-led care after ablation of atrial fibrillation improves short-term clinical outcome, patient satisfaction and physical activity and decreases alcohol intake.

- Our study shows that integrating nurse-led care in the post-AF ablation setting is a relatively simple to implement, low-cost intervention with a major impact on patient outcomes and quality of care. These findings encourage including nurse-led care into routine AF ablation follow-up.

Key words: Atrial fibrillation, pulmonary vein isolation, nurse-led care, advance practice nursing, nurse educator, recurrence.

1 Introduction

Catheter ablation mainly consisting of pulmonary vein isolation (PVI) is an established treatment for patients with symptomatic atrial fibrillation (AF) (1, 2). Despite rapid technical evolution and skill development, recurrence of AF is however seen in approximately 10-40% of the patients (2, 3). As a result, a repeat ablation is often required (4).

Over recent years, it has become clear that risk factors for the onset of AF, such as obesity, sleep apnoea syndrome (OSAS), smoking (5), alcohol consumption and physical inactivity also increase the likelihood of recurrence after ablation (6). Modification of these lifestyle factors forms the basis for the fourth pillar in AF treatment besides anticoagulation, rate- and rhythm control (6). Risk factors mentioned above are potentially reversible, unlike other risk factors such as age and gender (7). Studies show that with the reduction of alcohol consumption (8-10), weight loss (11, 12), treatment of OSAS (13), increased physical activity (14) and smoking cessation (15), the prognosis improves with a lower risk of recurrence of AF after ablation (16).

The latest European (European Heart Rhythm Association (EHRA)) and American (American Heart Association (AHA)), (17, 18) guidelines also emphasise the importance of patient education and patient-centredness ('shared decision-making') (19). This 'paradigm shift' in the treatment of AF, in which the patient is central to care coordination, opens a new domain. It requires education, helping care providers adapt to this new way of thinking, and organisation of a more accessible and closer follow-up (19).

However, the importance of education and lifestyle is currently underexposed in the follow-up of AF patients. The translation to clinical practice is, given the limited time, not obvious for the cardiologist during a routine consultation.

The potential value of nurse-led care by an advanced practitioner nurse (APN) in the follow-up after ablation has not been studied yet. Due to the decrease in hospital duration of patients at the time of ablation, providing the opportunity for patients to ask questions is becoming increasingly important.

The present study examined the value of adding nurse-led care to standard follow-up in patients undergoing AF ablation. The aim was to see whether a more intensive approach, i.e., follow-up by a cardiologist together with an APN (intervention group) led to less recurrence of AF and an improvement in lifestyle, patient satisfaction and knowledge about AF compared to the standard follow-up (usual care) after ablation.

2 Methods

2.1 Study participants and randomisation

From February 2021, every patient in the hospital of ZNA Heart Centre Middelheim, Antwerp, Belgium who underwent AF ablation (PVI using the cryoballoon, point-by-point PVI using radiofrequency (RF) energy or repeat ablation consisting of only re-isolation of reconnected pulmonary veins (PV) with no ablation beyond the PVs using RF energy) was screened for inclusion. No ablation beyond the PVs like atrial lines or ablation of complex fractionated electrograms was performed. Inclusion criteria were age 18 years or older, no cognitive impairments and no cardiac electronic assist device (pacemaker, defibrillator). Patients were prospectively randomised using a closed envelope system. An external hand pulled an envelope from a container for each new patient. When this envelope was opened, it was clear which group the enrolled patient belonged to.

A power analysis was priorly done using G*Power 3.1.9.7 (20). We estimated that 50 patients would be necessary to detect an effect size of 40% with an 80% power to reject the null hypothesis for a one-sided test and a type 1 error rate of 0.05 (21). Finally, we included 15 more patients to account for possible losses during follow-up. A total of 65 patients were included. Further details of inclusion are shown in Figure 1.

After patients were fully informed, they signed a written informed consent before the follow-up started. The study was approved by the ethical committee of the Antwerp Hospital Network (see appendix 1) which did not consider a clinical trial registration mandatory.

Figure 1: Flow diagram of screening, inclusion, and randomisation.

2.2 Outcomes

The primary outcome was the recurrence rate of documented AF, atrial flutter (AFL), atrial tachycardia (AT) after ablation during the six-month follow-up period.

Secondary outcomes were patient satisfaction (Patient-Reported Outcome Measurement (PROM)), AF knowledge and lifestyle factors (alcohol intake, exercise, BMI, smoking) measured at one and six months. An analysis was made of whether these outcomes differed between the intervention and usual care, and within each group.

2.3 Usual Care

After ablation, every patient, whether in the usual care or intervention group, received 'usual care.' This consisted of an offer to participate in the cardiac rehabilitation programme and a follow-up consultation by a cardiologist at one- and six-months post- ablation.

At the time of consultations at one and six months, patients were asked to complete a questionnaire, which contained questions gauging patients' knowledge of AF, possible triggering factors, and the

importance and use of new oral anticoagulants (NOACs). Furthermore, it included questions about patient experience during the hospitalisation and about the discharge procedure. Finally, it contained a section that had to be completed by the care-provider during consultation.

During consultations at one and six months after ablation, the evolution of symptoms was evaluated, a 12-lead ECG was taken, and, in case of persistent palpitations, a 24-hour-Holter or event recorder was planned to document the causative arrhythmia. AF recurrence was defined as a documented recurrence of AF, AFL or AT lasting for at least 30 seconds.

Co-morbidities such as OSAS, diabetes mellitus type 2 (DM II), hypertension (HT), dyslipidaemia and hyperthyroidism were annotated when present. Thromboembolic complications included both transient (transient ischaemic attack, TIA) and permanent ischaemic events (cerebrovascular accident, CVA). Clinical parameters such as blood pressure, height, weight, hip-waist ratio, and BMI were collected, as well as alcohol consumption, amount of exercise, units of smoking (where applicable) and medication were collected and monitored over time.

Outcomes of lifestyle were defined as follows: alcohol consumption was defined as units per week, physical activity (cycling, walking, or swimming) as minutes of exercise per week, smoking as number of units per day. AF knowledge was measured using the validated AF knowledge scale (22).

2.4 Intervention

The intervention group received nurse-led care that was given on top of usual care and comprised three main pillars: an educational session at the time of ablation, consultations at approximately two-, three- and six months and telephone availability during the study period. The nurse was an APN specialised in AF. The follow-up was inspired by the work of Berti et al. (23) and Hendriks et al. (24).

During the educational session, the importance of physical activity, reduction of alcohol intake, weight reduction, cessation of smoking and correct intake of NOAC's were briefly discussed. The patient's fears and insecurities were also discussed.

During APN consultations, all topics of the questionnaire (medication effects, knowledge of AF, possible complications of AF, weight, alcohol intake, smoking, physical activity) were discussed and it was determined what stage of behavioural change the patient was in (25). Oral information was provided in each patient according to EHRA guidelines (17). In case patients were willing to change for one of the lifestyle factors, resources such as the national eHealth (www.mijngezondheid.be) platform, which contains applications, websites, and organisations to improve physical activity, register blood pressure, register food intake were provided as well as relevant brochures developed in hospital about a specific topic.

if the patient indicated a willingness to change behaviour for one of the lifestyle factors. Results (glucose, lipids, renal function, thyroid function, and electrolytes) of the most recent blood samples were evaluated as well as underlying co-morbidities (OSAS, DM type II, HT, thyroid function, and dyslipidaemia).

In between these consultations, the APN was available by telephone to answer any further questions from the patients. These were often practical in nature, for example 'My doctor does not allow me to take my NOAC just before a certain procedure, is this correct?'

2.5 Statistical analysis

The Shapiro-Wilk test was performed to see if a variable was normally distributed.

Concerning the demographics, parametric variables were reported as mean ± standard deviation (SD), and nonparametric variables were reported as numbers and percentages. A Chi-squared or Fisher's exact test (n<30) was used to compare categorical or nominal variables and a student's t-test for continuous variables.

Firstly, recurrence of AF was analysed and a Kaplan-Meier survival analysis with a LogRank test was performed.

Next, patient satisfaction, AF knowledge and lifestyle outcomes were analysed. Differences between intervention and usual care group after six months' follow-up were measured using a Man-Whitney U test for non-parametric variables and a student's t-test for parametric variables. Within one group, differences between study entry and follow-up were analysed by a Wilcoxon signed rank test for nonparametric variables and a paired Student's t-test for parametric variables.

Finally, univariate, and multivariate regression analysis was performed to measure the influence of different variables (gender, type of AF, OSAS, DM type 2, age, BMI, systolic and diastolic blood pressure, weight, and alcohol intake) on recurrence.

A p-value below 0.05 (two-tailed) was considered statistically significant. IBM SPSS Statistics (version 26; SPSS Inc., Chicago, Illinois) was used for all statistical analyses.

3 Results

Baseline demographics for both groups are shown in Table 1. Baseline demographics for patient satisfaction, AF knowledge and lifestyle factors are shown in Table 2. Systolic blood pressure was significantly higher in the usual care group, respectively 144 vs. 133 ($p=0.028$). Age, gender, DM type II, OSAS, type AF and $CHADS_2VASC_2$ scores were not significantly different at baseline. Similarly, lifestyle factors such as alcohol consumption, smoking behaviour, physical activity, and BMI as well as participation in the cardiac rehabilitation programme were not different at one month evaluation. In contrast, knowledge of AF was statistically significantly higher in the intervention group at one month (8.2 vs. 7.5 out of ten ($p<0.001$)).

In seven control patients, ablation was performed using RF energy versus one in the intervention group ($p=0.026$) during the study period. This was due to a higher recurrence rate in the usual care group. In all other patients, ablation consisted of a pulmonary vein isolation using the cryoballoon catheter. Ablation in two out of the seven patients undergoing RF ablation in the usual care group was a repeat ablation ($p=0.03$).

Table 1: Baseline characteristics of participants in total and according to treatment group.

No statistical techniques were used to correct for missing and these were approached as missing at random.

3.1 Recurrence of AF/AFL/AT

At six months, sinus rhythm maintenance was significantly higher in the intervention group (87.5%) compared to the usual care group (60.6%) (p=0.014). The difference between the two groups is shown in Figure 2.

Figure 2: Kaplan-Meier estimates of recurrence of AF in both groups over six months.

3.2 Patient satisfaction

The increase in patient satisfaction in the intervention group (0.3 point, p<0.001), together with a slight, not significant decrease in the usual care group (-0.3 point, p=0.320), made a significantly higher patient satisfaction in the intervention group versus usual care group at six months (9.4 vs. 8.7, p<0.001) (see Table 2 and Figure 3).

3.3 AF knowledge

AF knowledge, shown in Table 2 and Figure 3, remained higher in the intervention group at six months (8.6 versus 7 out of ten, p<0.001). The AF knowledge score in the intervention group increased by 0.4, however this result was not significant. In contrast, there was a slight decrease of AF knowledge from a mean score of 7.5 to 7 in the usual care group, which was also not significant.

Table 2: Patient satisfaction, AF knowledge and lifestyle factors at one and six months and delta analysis to indicate the difference over time.

Figure 3: Evolution of lifestyle and patient satisfaction in both groups over six months.

3.4 Lifestyle

The evolution of lifestyle over the six-month follow-up is shown in Table 2 and Figure 3.

A decrease in mean alcohol consumption was most pronounced in the intervention group, from 3.9 to 2.6 units per week (p=0.031) versus from 5.5 to 5.2 units (p=0.510) in the usual care group. The overall difference over time between groups was -1.3 vs -0.3 units, however this was not statistically significant (p=0.246). Physical activity between groups remained not significantly different between intervention and usual care group at six months. However, in the intervention group, physical activity did increase significantly from 224.4 to 283.8 minutes per week (p=0.048). Physical activity of the usual care group slightly decreased by 11.3 minutes, but this result was not significant.
No significant differences were found between groups, nor within one group, in terms of weight and BMI. In addition, four patients, one in the intervention group and three in the usual care group, smoked and did not stop over the course of six months. Units of smoking increased in both groups not significantly, from 0.3 to 0.6 units (p=0.325) in the intervention group and from 1.2 to 1.6 units (p=0.592) in the usual care group.

3.5 Regression analysis

Univariate and multivariate analysis is shown in Table 3. Univariate analysis showed that the intervention group (Exp(B) 0.277) and alcohol consumption (Exp(B) 1.047) were significantly associated with the risk of AF recurrence (p=0.025 and p=0.025, respectively).

In the multivariate regression analysis with intervention group, sex, type of AF and alcohol intake, only assignment to the intervention group was a protective factor for AF recurrence (Exp(B) 0.299, p=0.04).

Table 3: Univariate and multivariate regression analysis of outcomes related to recurrence.

3.6 Workload and cost of the intervention

The APN saw about three study participants each Wednesday afternoon during the study period. These consultations lasted about 30 minutes per patient, for which 15 minutes preparation was needed. Two patients per week received the ten minutes educational session right before hospital discharge and each week, two patient calls were made of 15 minutes. The estimated cost for this work, calculated on three and a half hours of work per week and 24.9 euros salary per hour, is approximately 87 euros per week.

4 Discussion

4.1 Key findings

This prospective randomised study shows that the addition of a structured nurse-led follow-up care after ablation of AF improves short-term outcome with less recurrence of AF/AFL/AT (12.5%) compared to standard follow-up only (39.4%) (p=0.014). Assignment to the intervention group is the only predictor of less recurrence (Exp(B) 0.299, p=0.04). Between groups, patient satisfaction and AF knowledge were significantly higher in the intervention group at six months, respectively 9.4 vs. 8.7 (p<0.001) and 8.6 vs 7 out of 10 (p<0.001). Within the intervention group, alcohol intake decreased from 3.9 to 2.6 units per week (p=0.031) and physical activity increased significantly from 224.4±210.7 to 283.8±169.3 (p=0,048). No significant changes occurred within the usual care group. BMI and smoking behaviour remained unchanged.

4.2 Lifestyle and AF

Lifestyle change is not an easy task for patients, despite clear positive effects (16). At the moment, there is no consensus about the optimal way to guide patients in the adjustment of their lifestyle. Previous studies have examined the impact of intensive counselling programmes(12, 16).

The Active-AF study (14) examined the impact of a six-month exercise programme consisting of supervised and home aerobic exercise (target 3.5 hours of aerobic exercise per week) on recurrence of AF and symptom severity. In the intervention arm there was clearly decreased AF recurrence after 12 months compared to the control group (39.4% versus 12.5%, HR 0.50 (95% confidence interval (CI) 0.33–0.78; p=0.002).

The LEGACY study examined the effect of weight loss on rhythm control in 355 patients with AF (12). Three groups were created of which one group had to undergo a weight reduction of at least 10%. Groups two and three experienced a weight reduction of 3-9% and less than 3%, respectively. There was a significant reduction in AF and associated symptoms in the first group compared to the other two groups. Weight loss and weight fluctuations were the predictors of AF recurrence or antiarrhythmic drug use. Weight loss of 10% resulted in six times greater chance of freedom from AF (95% CI 3.4 to 10.3; p<0.001) compared to the other two groups.

The Arrest-AF study also examined an aggressive approach to weight reduction on the outcome of ablation in 149 patients with AF (16). Patients with a BMI of ≥27 kg/m2 and ≥ one risk factor according to the AHA guidelines (18) were followed after three and six months with a seven-day Holter. The intervention consisted of a physician-directed follow-up combined with blood-pressure monitoring three-times-daily, a personalised weight reduction programme, lipid monitoring, three-month glycaemia monitoring, a polysomnography to detect OSAS, and a systematic survey on smoking cessation. If treatment was required for any of these factors, it was applied. The control group consisted of the classic follow-up, in which the importance of risk factors was mentioned, but nothing further was done about it. The intervention group had a higher freedom from AF compared to the control group (p < 0.001).

In a prospective RCT, Voskoboinik et al. (10) studied the influence of abstinence or reduction in alcohol consumption on the risk of AF recurrence. One hundred and forty AF patients who consumed ten or more alcoholic drinks per week (one standard drink contains approximately 12 grams of pure alcohol), were randomised one on one to a group who abstained from alcohol (n=70),

or a group who maintained their normal alcohol intake, respectively (n=70). Alcohol consumption in the first group decreased by 87.5% from 16.8 (standard deviation of SD±7.7) to 2.1 (SD±3.7) units per week. Patients in this group also had a lower risk of AF recurrence (53% vs 73%, p=0.005), a longer time to onset of AF recurrence (hazard ratio (HR) 0.55; 95% CI, 0.36 to 0.84; p=0.005) and a lower AF time during the six-month follow-up (median % time of AF, 0.5% [interquartile range (IR), 0.0 to 3.0] vs. 1.2% [IR 0.0 to 10.3], p=0.010).

The translation of these intense counselling programmes from studies mentioned above into clinical practice is not easy. The intervention was always a very intensive follow-up with complex programmes to which patients had to adhere. In terms of intervention, however, the current study is based on, among others, the studies of Hendriks et al. (24, 26) and Berti et al. (23). This follow-up programme was less intense and less time consuming, but more practically feasible. In addition to an educational session after ablation, three additional consultations were organised, where the importance of lifestyle modification in patients with AF was stressed. Practical tools were offered to help with these changes. In this study, the APN appeared to increase patients' awareness of the influence of lifestyle on their physical condition and motivated and facilitated active behavioural change. Despite this lighter counselling programme, the drop-out of four patients after inclusion in the study was due to three additional consultations on top of the already intensive cardiac rehabilitation programme.

The results of the present study show that adding nurse-led counselling after ablation can encourage patients to reduce alcohol intake and increase physical activity. Furthermore, it leads to less recurrence of AF. No significant influence of a nurse-led follow-up on smoking and weight was found, likely due to the short study period. These may require more time than the six-month follow-up or potentially specific guidance programmes such as a smoking cessation programmes.

The present study adds to the expanding role of the APN in AF. This role has already been described by Berti et al. (23) focused towards a general follow-up. The present study, however, proves the

added value of specialised nurse-led care in the particular setting after ablation and encourages including nurse-led care into routine ablation follow-up.

Our study also shows that usual care by a cardiologist post PVI seems insufficient in promoting lifestyle modification. Organising a complementary pathway hosted by an advanced specialised AF nurse, prioritising risk factor education and post-ablation clinical lifestyle interventions, can fill this gap and improve outcomes. Integrating nurse-led care in the post-AF ablation setting is a relatively simple to implement, low-cost procedure with a major impact on patient outcomes and quality of care. It should be noted that this cost is sensitive to differences in policy implementation per country and that the role of advanced practitioner nurse in Belgium is currently in full development. Given the increase in the number of patients undergoing AF ablation procedures and the favourable results of this trial, time and cost of APN nursing can be expected to increase exponentially.

4.3 Patient-reported outcome measures

The importance of PROMs in the cardiovascular world has already been proven when wanting to provide patient-centred care (28). The positive influence of the APN on the follow-up of these PROMs has already been demonstrated (29). Patient satisfaction is reported as a PROM to evaluate the provided care (29) and has been previously measured in the study by Woo et al. (30). The nurse-led intervention group was significantly more satisfied with received care in this study compared to the control group that received a standard follow-up ($p<0.001$). In line with this, the current study also showed a significant improvement in patient satisfaction over the months in the nurse-led intervention group and decreased non-significantly in the control group.

4.4 Future prospects

Education by an APN and motivation for lifestyle change have contributed to a reduction of relapse. On the other hand, anxiety has been suggested to be an independent AF trigger (31, 32). Preoperative education has been proven to reduce anxiety (33) however, little is known about the influence of education on anxiety and patient outcomes after ablation.

In addition, adherence to therapy has an influence on recurrence (18). Adherence was not studied in this study, but it is an important task for the APN to monitor this.

4.5 Study limitations

Some limitations need to be acknowledged. The sample size of this study was relatively small and the follow-up over six months was relatively short, both influencing the regression analysis. A longer-term follow-up by an APN after ablation will show whether further improvement of lifestyle occurs and whether correction of weight and smoking behaviour is possible. A longer follow-up will also be able to show if our finding of an improved clinical outcome is sustained over time.

Furthermore, there was a significant difference between the groups at the start of the study in terms of AF knowledge. This may be due to the educational session of the APN immediately after ablation. Although previous research by Hendriks et al. (22, 24, 26) had already proven that the APN plays a role in increasing the patient's AF knowledge, this could not be demonstrated due to the already significant difference between the groups at the beginning of the study.

The statistically significant difference in systolic blood pressure between groups at baseline could indicate a larger left atrial size in the usual care group (34) and therefore partially explain the lower success rate. Evaluation of left atrial size by echo was not included in the study protocol. This is a limitation given the known powerful predictive role of left atrial size on AF ablation outcome. Of note, systolic blood pressure was included in the multiple regression analysis but was found non-significant.

There was potential bias as patients were aware that the focus was on lifestyle during the consultations. It is therefore possible that patients gave socially desirable answers. Bias could also not be ruled out among healthcare providers. They were aware of the study, as well as which study arm, they were in.

5 Conclusion

The current study shows a clear added value of a structured nurse-led follow-up of AF patients after ablation. The systematic approach to lifestyle through education, motivation, and facilitation of resources, reduced the risk of AF recurrence, increased patient satisfaction and improved lifestyle with a decrease in alcohol intake and increase in physical activity. This study shows the shortcomings of the current standard clinical follow-up of AF patients after ablation and further supports the growing scientific evidence for a shared follow-up by an APN in addition to a cardiologist as a new standard.

6 Funding and conflicts of interest

This trial was supported by the ZNA Heart Centre in Antwerp, Belgium. The Heart Centre did not influence study outcomes.

Conflict of interest: none declared.

7 Data availability statement

The data underlying this article will be shared on reasonable request to the corresponding author.

8 Authors' contributions

YDG and YV contributed to the conception of the work. YV, YDG, MW, BA, CC, MT, and BS contributed to the acquisition. JPADT, YDG and YV contributed to the data analysis and interpretation for the work. YV and YDG drafted the manuscript. YDG, PVB and EG critically revised the manuscript. All gave final approval and agreed to be accountable for all aspects of work ensuring integrity and accuracy.

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10 Table and Figure legends

Figure 1: Flow diagram of screening, inclusion, and randomisation.

Table 1: Baseline characteristics of participants in total and according to treatment group.

Data is presented as the mean value ± SD or number (%) of patients. SD: standard deviation; BMI: Body Mass Index; PA: physical activity; CRP: cardiac rehabilitation programme; AF: atrial fibrillation; m-EHRA score: modified European Heart Rhythm Association score; pers: persistent; RF: radio frequency ablation; OSAS; obstructive sleep apnoea syndrome; DM II: diabetes mellitus type 2; AC: anticoagulants; NOAC: new oral anticoagulant; VKA: vitamin-K antagonists; polypharmacy: patient takes five or more medications; TE: thrombo-embolic.

Figure 2: Kaplan-Meier estimates of recurrence of AF in both groups over six months.

AF: atrial fibrillation; AFL: atrial flutter; AT: atrial tachycardia.

Table 2: Patient satisfaction, AF knowledge and lifestyle factors at one and six months and delta analysis to indicate the difference over time.

Date is presented as mean ± standard deviation. Patient satisfaction and patient knowledge: score out of ten. Alcohol intake: units per week. Physical activity: minutes per week. BMI: body mass index, kg/m^2. Smoking: units per day. SD: standard deviation.

Figure 3: Evolution of patient satisfaction, AF knowledge and lifestyle factors in both groups at one and six months.

Alcohol intake: units per week. Physical activity: minutes per week. Smoking: units per day. Patient satisfaction and AF knowledge: score out of ten. BMI: Body Mass Index; AF: atrial fibrillation.

Numbers rounded to decimals.

 = intervention group, n=32  = usual care group, n=33

Table 3: Univariate and multivariate regression analysis of outcomes related to recurrence.

OSAS: obstructive sleep apnoea syndrome; DM II: diabetes mellitus type 2; BMI: body mass index.

Graphic element: Legend of abbreviations. AF: atrial fibrillation; AFL: atrial flutter; AT: atrial tachycardia; PVI: pulmonary Vein Isolation; APN: Advances Practicioner Nurse; Alcohol intake: units per week; Physical exercise: minutes per week; Patient satisfaction and AF Knowledge scale: score out of 10. Numbers rounded to decimals.

 = intervention group, n=32  = usual care group, n=33

11 Appendices

11.1 Ethical committee approval

ETHICS COMMITTEE JUDGEMENT

On October 14, 2020, the Commissie voor Medische Ethiek ZNA,

Institutional Review Board – ZNA/OCMW Antwerpen, Lindendreef 1, 2020 Antwerpen,

(Erkenning nr. 009; OG 031), has examined the following protocol:

Protocol title:	Meerwaarde van een gespecialiseerde AF verpleegkundige op cardiovasculaire patiëntuitkomsten bij post-ablatie patiënten.
Protocol number:	Version: 1
Eudract number:	B0092020000018
Protocol date:	May 31, 2020
Pharm. company:	UA
Submitted by:	dr. Y. Vanharen, dr. Y. De Greef, ZNA Middelheim

Type of protocol judgement:

■ initial ☐ continuing ☐ protocol amendments ☐ end of study

Following documents have been submitted as required by European Directive 2001/20/EC and as stated in the Belgian law regarding experiments in humans dd. 07.05.2004:

■ protocol, version 1 dd. 05.2020

☐ investigators brochure

■ informed consent document, Dutch version 1 dd. 02.09.20

- accuracy
- completeness
- comprehensibility

■ insurance declaration, from 01.01.20 to 31.12.20 dd. 12.11.19

☐ amendment

■ CV dr. Y. De Greef, signed off dd. 03.09.20

■ CV mevr. Y. Vanharen, signed off dd. 22.08.20

The Committee has decided that:

■ the study is ethically acceptable without reserve.

☐ the study is ethically acceptable, taking into account the comments specified in the accompanying letter.

☐ this study is currently ethically not acceptable, due to the comments specified in the accompanying letter.

☐ more information, specified in addendum, will be necessary, to evaluate this study.

☐ the amendment has been accepted/rejected/well received/notified.

THIS RECOMMENDATION IN NO SENSE MEANS THAT THE COMMITTEE IS RESPONSIBLE FOR THIS STUDY.

Signature chairman Signature secretary Date: 14.10.2020

Prof. Dr. P.P. De Deyn Prof. Dr. ir. G. Nagels **E.C. APPROVAL N° 5421**

12 Tables

Table1: Characteristics of participants in total and according to treatment group.

	Total (N=65)	Usual care (N=33)	Intervention group (N=32)	P-value
Age, years, M±SD	65.3±10,5	64.7±10.2	65.9±10.9	0.645
Sex, male, N (%)	36(55.4)	18(54.5)	18(56.3)	0.890
Length, cm, M±SD	175.0±10.3	174.5±10.3	175.5±0.4	0.676
Weight, kg, M±SD	89.1±16.3	88.8±16.4	89.4±16.6	0.899
Blood pressure				
Systolic, mmHg, M±SD	139.1±21.7	144.1±22.3	133.2±19.6	**0.028**
Diastolic, mmHg, M±SD	80.9±10.4	83.1±11.8	78.6±8.9	0.084
CRP, N (%)	23(35.4)	11(33.3)	12(37.5)	0.725
$CHADS^2VASC^2$-score, M±SD	2.2±1.7	2.0±1.6	2.4±1.7	0.372
m-EHRA-score, M±SD	1.4±1.3	1.6±1.3	1.2±1.3	0.264
RF-ablation, N (%)	8(12.3)	7(21.2)	1(3.1)	**0.026**
Type AF, pers, N (%)	23(35.4)	13(39.4)	10(31.3)	0.492
Type AF, paroxysmal, N (%)	42(64.6)	20(60.6)	22(68.8)	0.492
OSAS, N (%)	7(10.8)	3(9.1)	4(12.5)	0.658
DM II, N (%)	5(7.7)	3(9.1)	2(6,3)	0.667
AC				0.230
NOACs, N (%)	59(90.8)	28(84.8)	31(96,9)	
VKAs, N (%)	1(1.5)	1(3.0)	0(0.0)	
No AC, N (%)	5(7.7)	4(12.1)	1(3.1)	
Polypharmacy, N (%)	27(41.5)	12(36.4)	15(46.9)	0.390
Bèta-blockers, N (%)	52(80.0)	24(72.7)	28(87.5)	0.137
Anti-arrythmic drugs N (%)	26(40.0)	13(39.4)	13(40.6)	0.919
TE complication, N (%)	1(1.5)	1(3.0)	0(0.0)	0.321

Table 2: Patient satisfaction, AF knowledge and lifestyle factors at one and six months and delta analysis to indicate the difference over time.

	1 month			6 months			Difference		
	Intervention	**Usual care**	**P-value**	**Intervention**	**Usual care**	**P-value**	**Intervention**	**Usual care**	**P-value**
Patient satisfaction, ± SD	9.1±0.8	9.0±1.1	0.621	9.4±1.8	8.7±1.1	**<0.001**	0.3±2.1	-0.3±1.1	0.236
Patient knowledge, ± SD	8.2±1.8	7.5±1.8	**<0.001**	8.6±1.8	7.0±1.8	**<0.001**	0.4±2.2	-0.5±1.8	0.073
Alcohol intake, ± SD	3.9±5.3	5.5±9.7	0.411	2.6±3.7	5.2±9.5	0.277	-1.3±3.6	-0.3±2.9	0.246
Physical activity, ± SD	224.4±210.7	271.7±279.2	0.433	283.8±169.3	260.3±319.4	0.154	59.4±177.0	-11.4±164.7	0.100
BMI, ± SD	28.9±4.1	29.2±4.7	0.785	27.6±6.5	27.9±6.6	0.728	-1.2±4.7	-1.3±6.2	0.978
Smoking, ± SD	0.3±1.8	1.2±4.3	0.333	0.6±3.5	1.6±7.4	0.329	0.3±1.8	0.4±0.3	0.919

Table 3: Univariate and multivariate regression analysis of outcomes related to recurrence.

Univariate analysis

	P-value	Exp(B)	95.0% CI for Exp(B)	
			Lower	Upper
Intervention group	**0.025**	0.277	0.090	0.851
Sex, male	0.069	0.397	0.147	1.075
Type of AF, persistent	0.083	2.321	0.895	6.019
OSAS	0.604	1.478	0.338	6.464
DM II	0.781	0.751	0.100	5.662
Age	0.217	1.031	0.982	1.082
BMI	0.813	1.009	0.936	1.088
Systolic blood pressure	0.330	1.012	0.988	1.037
Diastolic blood pressure	0.896	1.003	0.962	1.046
Weight	0.240	0.982	0.951	1.013
Alcohol consumption	**0.025**	1.047	1.006	1.090
Repeat ablation	0.247	3.300	0.437	24.931

Multivariate analysis

	P-value	Exp(B)	95.0% CI for Exp(B)	
			Lower	Upper
Intervention group	**0.040**	0.299	0.094	0.945
Sex, male	0.064	0.387	0.141	1.057
Type of AF, persistent	0.232	1.847	0.676	5.049
Alcohol consumption	0.293	1.022	0.981	1.065

13 Figures

Figure1: Flow diagram of screening, inclusion, and randomisation.

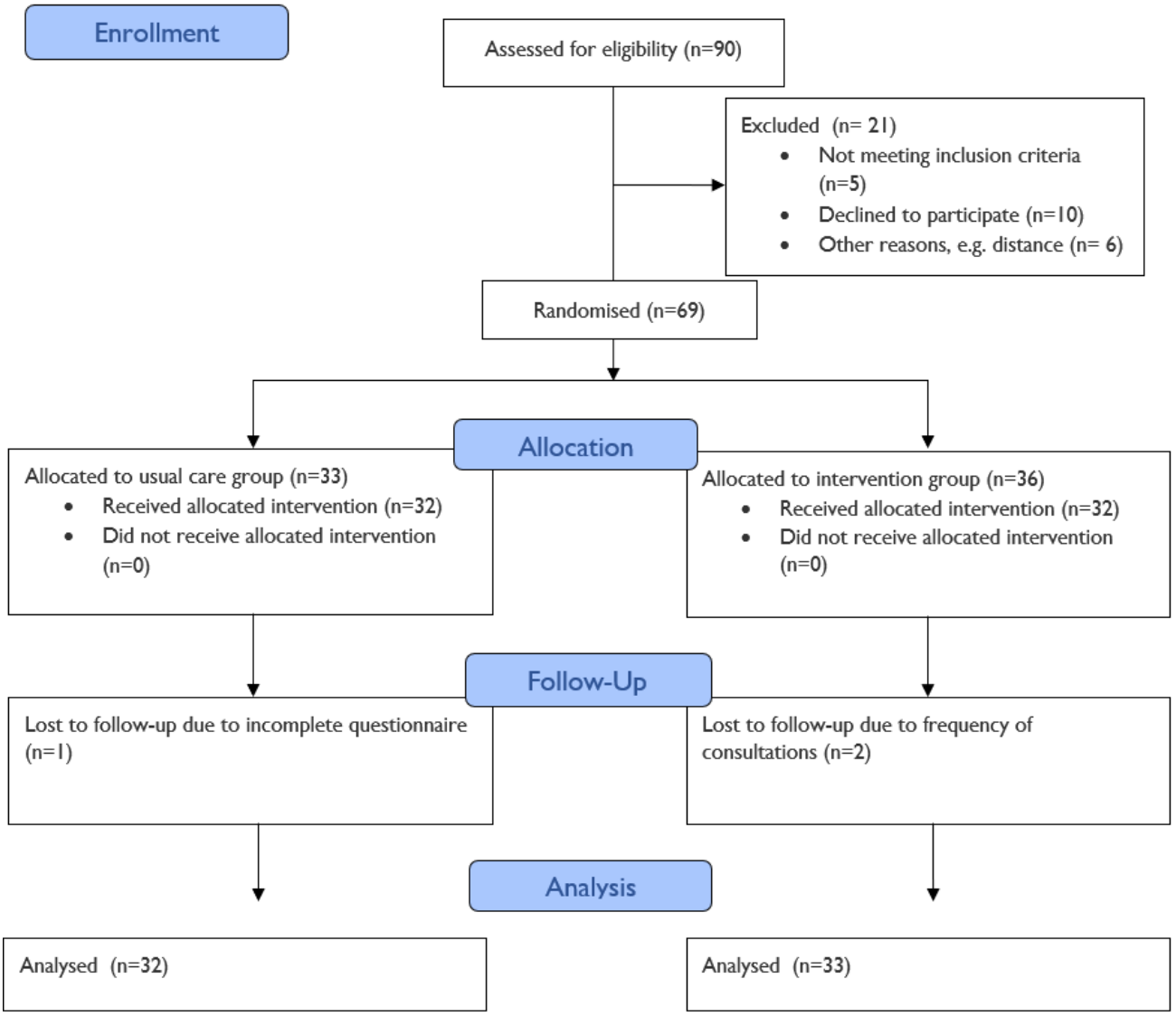

Figure 2: Kaplan-Meier estimates of recurrence of AF in both groups over six months.

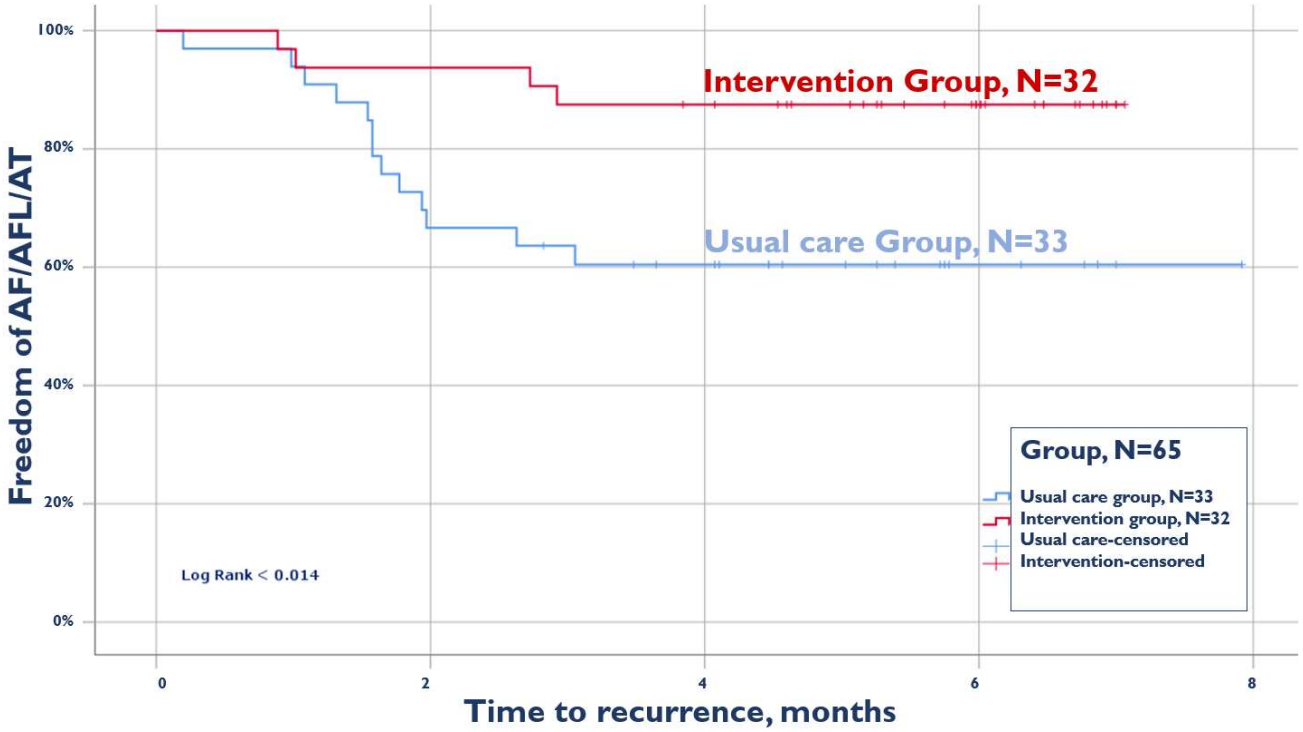

Figure 3: Univariate and multivariate regression analysis of outcomes related to recurrence.