

## Research Article

# Quality of Life in Patients with Atrial Fibrillation after Percutaneous Left Atrial Appendage Closure

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## Abstract

**Introduction:** Atrial Fibrillation (AF) and its possible complications have a significant impact on the Quality of Life (QoL). Percutaneous Left Atrial Appendage Closure (LAAC) is a procedure dedicated to patients with AF and contraindication to anticoagulation or failure of this therapy in prevention of thromboembolic events.

**Aim:** To determine QoL in patients with AF after trans catheter LAAC.

**Methods:** 25 adult patients (10 F, 15 M) with a mean age of 68, 16 ± 8, 23 (49-83) who underwent LAAC were enrolled into the study. QoL was measured using the SF36 questionnaire (SF36q). Scores were transformed to a scale of 0-100, where higher scores represent higher functioning. The items were assigned to 8 domains: Physical Functioning (PF), Role-Functioning (RP), Bodily Pain (BP), General Health (GH), Vitality (VT), Social Functioning (SF), Role-Emotional (RE) and Mental Health (MH). SF36q, clinical examination and echocardiography were performed before the procedure, as well as after the following 45 days, 3 months and 12 months.

**Results:** The LAA device was implanted in all patients (Watchman device – 19 pts, Amplatzer Amulet LAAC device – 6 pts). 5 of 8 QoL parameters improved significantly ( $p < 0,05$ ) at 12 month follow-up compared to respective baseline values. The mean SF36q scale increased from 50, 3 points to 65, 25 points after 12 months. There was no significant correlation between the indications for procedure, sex or type of implanted device.

**Conclusions:** Transcatheter LAAC resulted in improvement of the quality of life, measured by SF36 questionnaire at 12-month follow-up.

**Keywords:** Atrial fibrillation; Percutaneous left atrial appendage closure; Quality of life; Thromboembolism

## Abbreviations

AF: Atrial Fibrillation; QoL: Quality of Life; LAAC: Left Atrial Appendage Closure; SF36q: QoL was measured using the SF36 questionnaire; PF: Physical Functioning; RP: Role-Functioning; BP: Bodily Pain; GH: General Health; VT: Vitality; SF: Social Functioning; RE: Role-Emotional; MH: Mental Health; CAD: Coronary Artery Disease; CKD: Chronic Kidney Disease; LAA: Left Atrial Appendage; TEE: Trans Esophageal Echocardiography; TTE: Trans Thoracic Echocardiography; ACP: Amplatzer Cardiac Plug; ESC: European Society of Cardiology; SF-12v2: To assess the QoL the Short-Form 12 Health Survey version 2

## Introduction

Atrial Fibrillation (AF) is the most common cardiac arrhythmia. Prevalence of AF in adult population amounts to 3% and increases with age and comorbidities such as hypertension, heart failure, Coronary Artery Disease (CAD), valvular heart disease, obesity, diabetes mellitus, or Chronic Kidney Disease (CKD). AF is associated with five-fold higher risk of ischemic stroke whether it is a paroxysmal, persistent or permanent arrhythmia [1-3]. Prevention of stroke and systemic thromboembolism is of paramount importance in patients with AF [4]. Both - anticoagulation therapy and complications of this

treatment such as hemorrhagic stroke or gastrointestinal bleeding significantly influence QoL [5]. Left atrial appendage occlusion is the procedure indicated for patients with nonvalvular AF and ineffective anti-thrombotic therapy or contraindications to anticoagulation. Several studies revealed that percutaneous LAAC is highly effective in patients with AF and contraindications to anticoagulation treatment as prevention of thromboembolic events [6]. Despite encouraging results of the previous trials, the procedure continues to be evaluated by clinicians with focus on its safety, efficiency, cost-effectiveness and impact on QoL.

## The Aim of the study

Was to determine the quality of life in patients after transcatheter LAAC and to compare self-rating of patients and echo cardio graphic findings in a 45-day, 3-month and 12-month follow-up.

## Material and Methods

### Study population

The group enrolled into the study consisted of 25 adult patients (10 F, 15 M, mean age 68,16 ± 8,23 years, range 49-83) with nonvalvular AF (permanent - 11; persistent - 3; paroxysmal - 11), highly risk of ischemic stroke (mean CHA<sub>2</sub>DS<sub>2</sub>-VASc score 3,76 ±

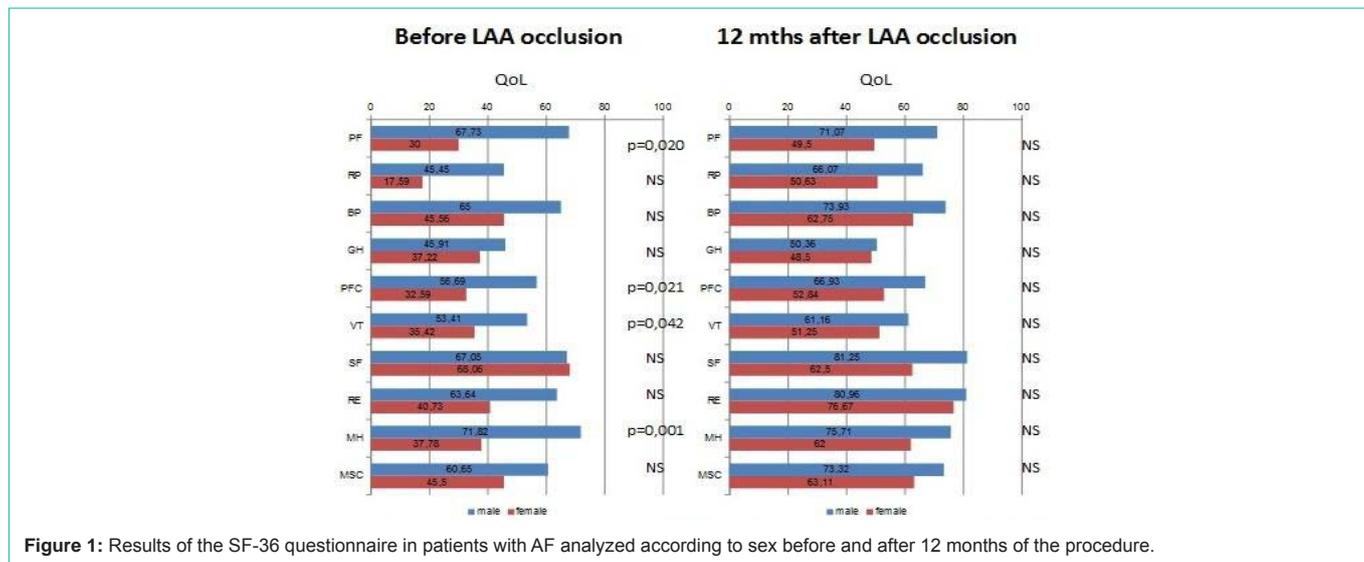


Figure 1: Results of the SF-36 questionnaire in patients with AF analyzed according to sex before and after 12 months of the procedure.

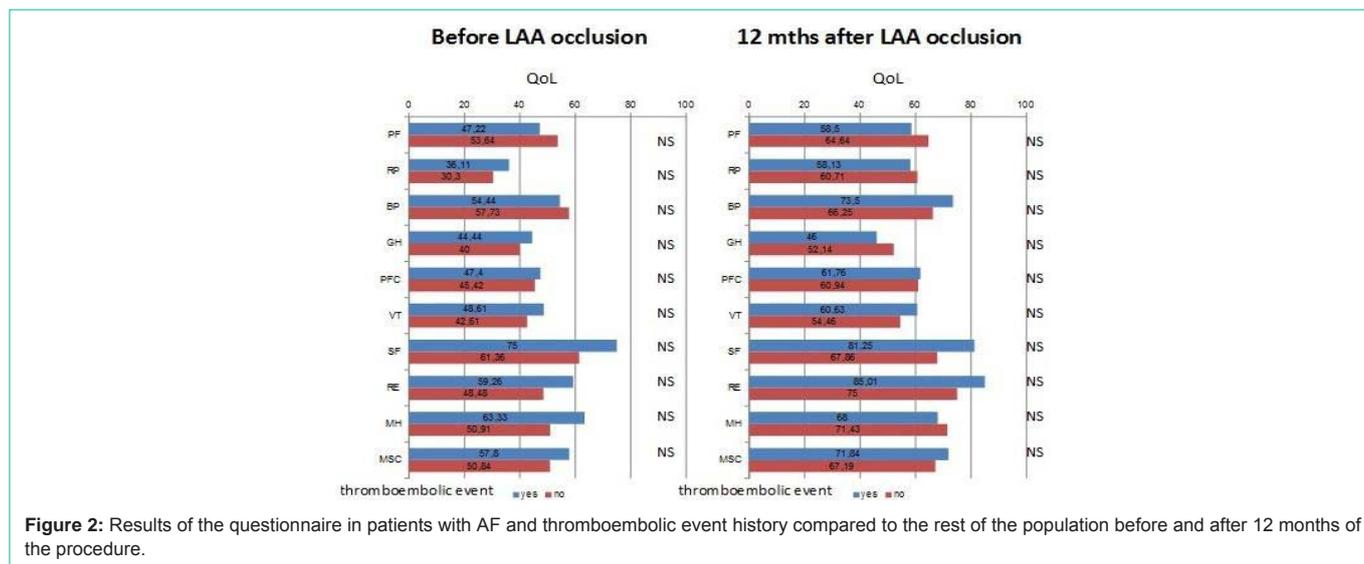


Figure 2: Results of the questionnaire in patients with AF and thromboembolic event history compared to the rest of the population before and after 12 months of the procedure.

1,74) and ineffective anti-thrombotic therapy or contraindications to anticoagulation (mean HAS-BLED score  $3,24 \pm 1,01$ ) who underwent transcatheter LAAC between August 2014 and June 2016. Table 1 presents clinical and demographic characteristic of study population. The exclusion criterion was valvular AF.

**The procedure**

The methods of transcatheter closure were described before [7-9]. The procedure was performed using Watchman device (19 pts, 76%) or Amplatzer Amulet LAAO device (6 pts, 24%). Before the procedure all patients had trans esophageal echocardiograms performed to evaluate the morphology of the Left Atrial Appendage (LAA) and exclude the presence of a intra cardiac thrombi. The procedure was performed under general anesthesia with TEE guidance. The device was delivered via right femoral vein puncture.

**Quality of life**

Quality of life was measured using the SF36 questionnaire (SF36q). Scores were transferred to a scale of 0-100, where higher

scores represent higher functioning. The items were assigned to 8 domains: Physical Functioning (PF), Role-Functioning (RP), Bodily Pain (BP), General Health (GH), Vitality (VT), Social Functioning (SF), Role-Emotional (RE) and Mental Health (MH). The first of these four elements (PF, RP, BP, GH) create Physical Component Summary (PCS), the other four (VT, SF, RE, MH) - Mental Component Summary (MCS).

**Follow-up**

SF36q evaluation was repeated in all patients after 45 days, 3 months and 12 months of follow-up. All patients were subjected to clinical examination, Trans Esophageal Echocardiography (TEE) 45 days after the procedure, and Trans Thoracic Echocardiography (TTE) 3 months and 12 months after the procedure.

**Statistical analysis**

All values are presented as mean and SD and Median with min-max. Normal distribution was analyzed with the Shapiro-Wilk test. Because of the lack of normal distribution in analyses, subgroups

**Table 1:** Demographic and clinical characteristics of patients.

	All patients (n=25)	Watchman group (n=19)	Amulet group (n=6)
Age (years)	68,16 ± 8	66,6 ± 8,28	73,17 ± 9
Sex (male/female)	15/10	12/7	3/3
Time of hospitalization (days)	3-22 (8,48 mean)	3-22 (8,2 mean)	5-19 (9,3 mean)
Coronary artery disease (n/%)	7/28%	4/21%	3/50%
Heart failure (n/%)	3/12%	3/15,8%	0/0%
LVEF	59,56 ± 4,75	59,4 ± 5,2	60 ± 3,16
Hypertension (n/%)	19/76%	15/78,9%	4/66,7%
Diabetes mellitus (n/%)	9/36%	7/36,8%	2/33,3%
CHA <sub>2</sub> DS <sub>2</sub> -VASc score	3,76 ± 1,7	3,5 ± 1,7	4,7 ± 1,5
HAS-BLED score	3,24 ± 1	3,1 ± 0,9	3,7 ± 1,2
Stroke/TIA despite anticoagulation therapy (n/%)	9/36%	5/26,3%	4/66,7%
Severe hemorrhage during anticoagulation therapy (n/%)	16/64%	14/73,7%	2/33,3%

**Table 2:** Comparison of the quality of life domains in the study population (baseline vs. one year after LAAC).

	Before LAA occlusion	45 days after LAA occlusion	3 months after LAA occlusion	12 months after LAA occlusion	p value before vs 45 days	p value before vs 3 month	p value before vs 12 month
PSC	46,4 ± 24,4	55,1 ± 27,2	55,2 ± 26,8	61,3 ± 24,2	p=0,049	p=0,020	<b>p=0,002</b>
	47,5 (11,3-88,8)	58,1 (10,6-95,0)	56,3 (6,9-93,8)	63,1 (11,9-97,5)			
MCS	54,2 ± 23,8	65,0 ± 23,0	66,5 ± 21,2	69,2 ± 21,5	NS	p=0,048	<b>p=0,001</b>
	60,3 (19,7-86,3)	70,3 (14,1-98,4)	71,9 (25,2-98,4)	76,9 (24,3-100)			
PF	50,8 ± 34,0	58,8 ± 32,6	58,7 ± 33,0	62,1 ± 29,4	NS	p=0,023	NS
	42,5 (0-100)	60,0 (0-100)	55,0 (0-100)	65,0 (0-100)			
RP	32,9 ± 34,5	52,9 ± 41,3	55,3 ± 43,8	59,6 ± 37,3	NS	NS	<b>p=0,008</b>
	25,0 (0-100)	50,0 (0-100)	75,0 (0-100)	59,4 (0-100)			
BP	56,3 ± 32,5	63,2 ± 35,1	64,5 ± 34,7	69,3 ± 30,5	NS	NS	<b>p=0,010</b>
	52,5 (0-100)	57,5 (0-100)	57,5 (0-100)	70,0 (12,5-100)			
GH	42,0 ± 17,2	45,6 ± 21,6	42,4 ± 18,9	49,6 ± 18,1	NS	NS	NS
	42,5 (10,0-70,0)	40,0 (15,0-80,0)	40,0 (10,0-80,0)	45,0 (20,0-90,0)			
VT	45,3 ± 17,3	52,2 ± 26,3	53,4 ± 24,5	57,0 ± 26,3	NS	NS	<b>p=0,029</b>
	43,8 (25,0-75,0)	56,3 (6,3-93,8)	56,3 (12,5-93,8)	62,5 (6,3-100)			
SF	67,5 ± 29,6	74,3 ± 29,1	75,0 ± 26,7	73,4 ± 28,4	NS	NS	NS
	68,8 (12,5-100)	87,5 (12,5-100)	75,0 (25,0-100)	75,0 (12,5-100)			
RE	53,3 ± 46,4	66,7 ± 40,8	70,2 ± 36,7	79,2 ± 31,9	NS	NS	<b>p=0,014</b>
	50,0 (0-100)	100 (0-100)	100 (0-100)	100 (0-100)			
MH	56,5 ± 25,2	66,8 ± 20,7	67,5 ± 18,6	70,0 ± 18,6	NS	p=0,048	<b>p=0,026</b>
	55,0 (10,0-100)	75,0 (25,0-100)	70,0 (30,0-100)	70,0 (35,0-100)			

PSC: Physical Component Summary; MCS: Mental Component Summary; PF: Physical Functioning; RP: Role Physical; BP: Body Lity Pain; GH: General Health; VT: Vitality; SF: Social Functioning; RE: Role Emotional; MH: Mental Health

Mann-Whitney U test and Wilcoxon signed rank test were used. Figures are based on mean values. A value  $p \leq 0,05$  was considered statistically significant. Statistical 12 software (Stat Soft Polska) was used to analyze the data. To compare the change in quality of life the data were analyzed taking into account age, indications for the procedure and type of implantable devices.

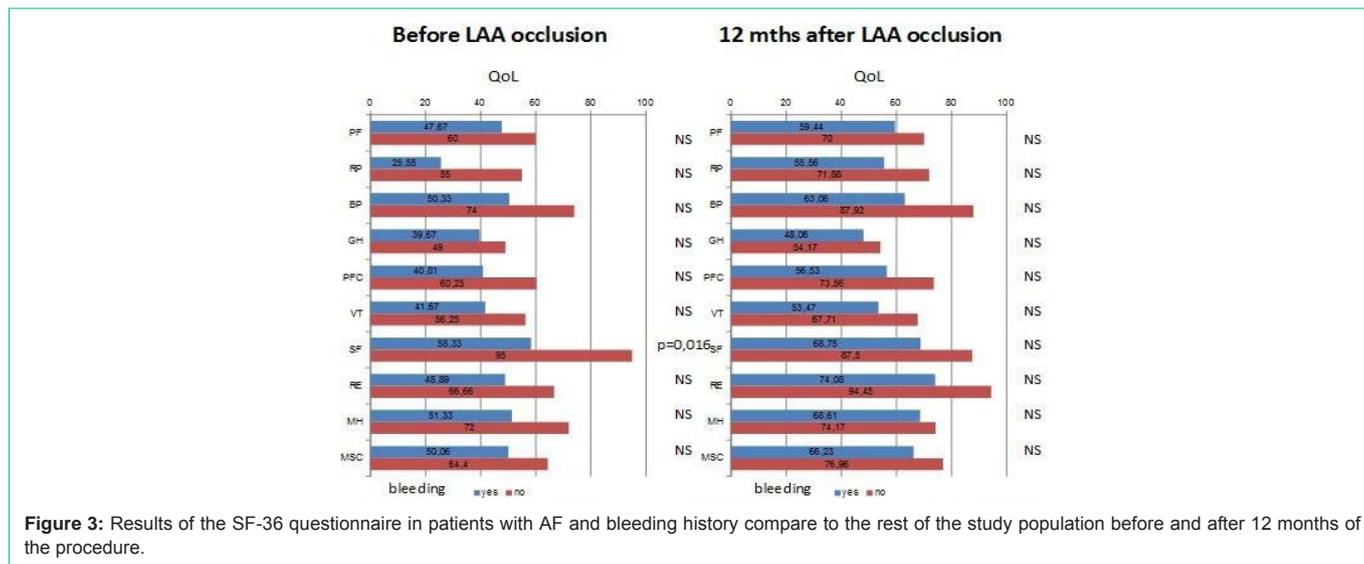
## Results

### Clinical results of LAAC

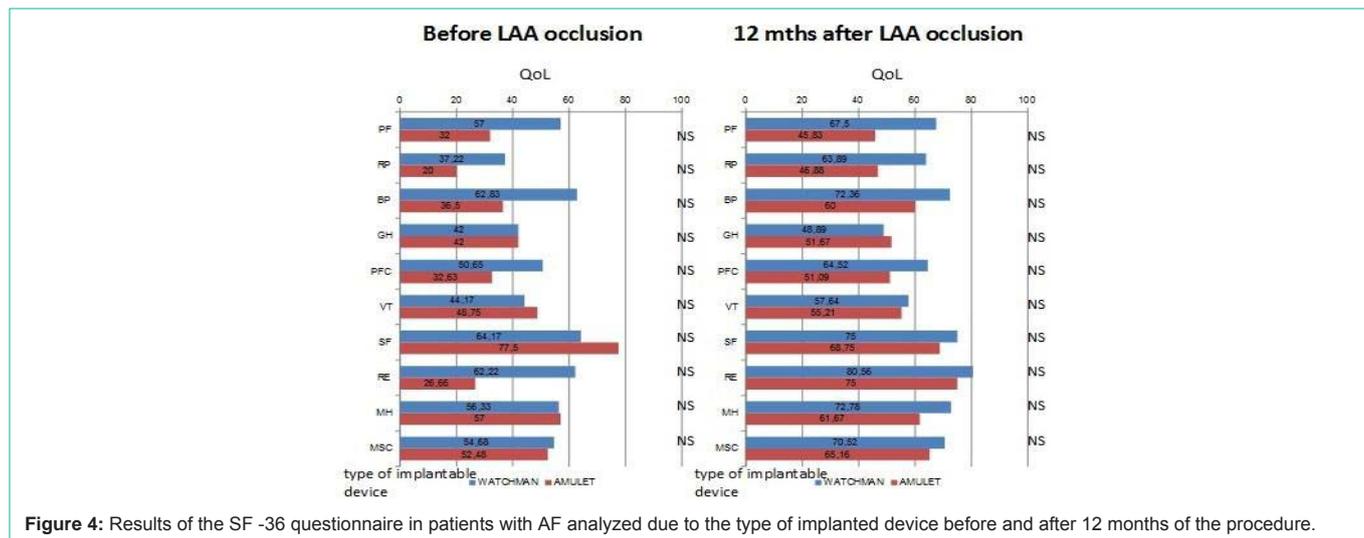
The devices were successfully implanted in all patients. 19 patients

(76%) underwent implantation of Watchman device, 6 patients (24%) were implanted with Amplatzer Amulet LAAO device. One implantation was complicated by pericardial tamponade. 5 days after procedure, and was successfully treated with pericardiocentesis. In this case, there was no damage of left atrial wall around the implanted device.

45 days after the procedure all patients underwent controlled TEE. The examination revealed minimal residual shunt (defined as peri-device leak  $< 5$  mm) in 2 patients (8%) which disappeared over 3-month follow-up. In 1 patient (4%) TEE showed device-related



**Figure 3:** Results of the SF-36 questionnaire in patients with AF and bleeding history compare to the rest of the study population before and after 12 months of the procedure.



**Figure 4:** Results of the SF-36 questionnaire in patients with AF analyzed due to the type of implanted device before and after 12 months of the procedure.

thrombus. Anticoagulation therapy with therapeutic dose of low molecular weight heparin guided by anti-Xa assay resulted in clot resolution during 6-month follow-up.

12 months after the procedure TTE revealed proper position of implanted devices in all groups of patients. No residual shunts, thrombi or pericardial fluid were observed.

**QoL before and after LAAC**

After 12-month follow-up, the average SF36q score increased in all subscales. Statistically significant change occurred in five subcategories of SF36q: Role Physical (RP), Bodily Pain (BP), Vitality (VT), Role Emotional (RM) and Mental Health (MH) compared to their baseline values (Table 2). The improvement was also noticed in PSC and MSC which contain all eight domains of the SF-36q.

There were no significant differences in subgroups of patients regarding sex, indications for procedure (bleeding or thromboembolic events) and type of implanted device. None of the domains showed statistically significant differences in QoL before and after one year from the procedure. Figures 1-4 depict the results of statistical

analysis.

**Discussion**

The occurrence of complications of AF such as thromboembolic events or bleeding caused by anticoagulation therapy significantly reduces the quality of life of people in all its areas [10-13].

LAA is the main site of thrombi formation. In patients with non-valvular AF over 90% of blood clots originate from LAA [14,15]. Isolation of LAA (surgical exclusion or percutaneous closure) is the procedure dedicated to patients with nonvalvular AF and ineffective anti-thrombotic therapy or contraindications to anticoagulation. Percutaneous LAAC is a nonsurgical, minimally invasive catheter-based intervention. This procedure has been performed since 2001 when the first device was successfully implantable. There are several types of devices used. The widest clinical experience reported to date concerned the Watchman and Amplatzer Cardiac Plug/Amulet. Watchman device (Boston Scientific, Massachusetts, and USA) has been evaluated in several clinical trials and studies (PROTECT AF study, PROTECT AF Long Term Study, PREVAIL study,

ASAP study) which confirmed its clinical efficacy in prevention of stroke and systemic thromboembolism. Amplatzer Cardiac Plug (ACP) and Amulet devices - second generation of ACP (St. Jude Medical, Minnesota, and USA) have been investigated in several studies – the biggest study was multicentre registry including 1047 patients from 20 international centres [7-9]. The type and size of the implantable device depends on the LAA morphology [16]. The recent European Society of Cardiology (ESC) guidelines from 2016 on the Management of Atrial Fibrillation recommend occlusion of LAA in stroke prevention for patients with AF and contra-indications to long-term anticoagulation (IIb, level C) [17].

The biggest clinical study evaluative QoL in patients with nonvalvular AF was the trial “Quality of Life assessment in the randomized PROTECT AF” comparing quality of life in patients treated by percutaneous LAAC by Watchman device versus warfarin in therapy. To assess the QoL the Short-Form 12 Health Survey version 2 (SF-12v2) similar to SF-36q was using. The results showed significant improvement in QoL especially in physical functioning in patients randomized to device group. The study also found a decrease in QoL in patients on chronic warfarin in therapy [8,18]. Despite of we used another test to evaluate QoL, results of our survey are comparable to results of PROTECT AF trial.

In our prospective study, we compared QoL in patients with nonvalvular AF who underwent percutaneous LAAC. Before the procedure, all of the patients presented lower than expected results in all domains of the SF-36q. After one year of follow-up we notified increase in the average score in mental (MSC - 32% improvement) and physical component (PSC - 27% improvement) of QoL. Five from eight subscales increased significantly compared to baseline date. Limitations of our study were number of patients and heterogeneous population with multiple co-morbidities having a significant impact on QoL. Our results are comparable to results of previous study [8,18]. The most important issue, which has to impact of QoL in patients with non-valvular AF after LAAC, is possibility to elimination of chronic anticoagulation therapy. Indication for the procedure, sex and type of implantable devices do not have a significant impact on QoL.

Our study results demonstrate that device closure of LAA is the procedure that should be considered in patients with AF not only due to the impact of reduced risk of ischemic stroke and bleeding complications, but also in connection to its impact on QoL. The study of Quality of Life in patients with atrial fibrillation after percutaneous left atrial appendage closure is needed on the biggest group of patients.

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