ORIGINAL ARTICLE

Comparative effectiveness and safety of antazoline-based and propafenone-based strategies for pharmacological cardioversion of short-duration atrial fibrillation in the emergency department

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KEY WORDS

ABSTRACT

antazoline, atrial fibrillation, comparative effectiveness, pharmacological cardioversion, propafenone

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Michał M. Farkowski, MD, PhD, II Klinika Choroby Wieńcowej, Instytut Kardiologii, ul. Spartańska 1, 02-637 Warszawa, Poland, phone: +48 22 343 40 50, e-mail: mfarkowski@gmail.com Received: February 24, 2016. Revision accepted: May 4, 2016. Published online: June 24, 2016. Conflict of interest: none declared. Pol Arch Med Wewn. 2016; 126 (6): 381-387 doi:10.20452/pamw.3452 Copyright by Medycyna Praktyczna, Kraków 2016 **INTRODUCTION** Numerous studies described the effectiveness and safety of antazoline in pharmacological cardioversion of short-duration atrial fibrillation (AF). However, there are no data on the comparison of antazoline and antiarrhythmic drugs listed in clinical guidelines.

OBJECTIVES The aim of the study was to assess the comparative effectiveness and safety of antazoline--based and propafenone-based strategies in pharmacological cardioversion of short-duration AF performed in our emergency department.

PATIENTS AND METHODS We conducted a retrospective case-control study based on the analysis of medical records of patients undergoing pharmacological cardioversion of short-duration AF with intravenous antazoline or propatenone at our department in the years 2008–2012. The primary endpoint was the successful cardioversion of AF. The primary safety endpoint was hospitalization due to the adverse effects of the treatment.

RESULTS We analyzed 432 cases of cardioversion. The mean age of patients was 68.9 ± 9.8 years; 65% of the patients were male; 90% of the patients had a history of AF. Antazoline was administered 334 times and propafenone—98 times. The mean dose of antazoline was 172 ± 65 mg, while all patients in the propafenone group received the drug at a fixed dose of 70 mg (1 vial). Cardioversion with antazoline was successful in 239 cases (71.6%) and with propafenone—in 54 patients (55.1%) (relative risk [RR], 1.30; 95% confidence interval [CI], 1.07-1.57). The rate of hospitalization due to the adverse effects of the treatment were low and similar between the study groups: 10 (3.0%) for antazoline and 4 (4.1%) for propafenone (RR, 0.73; 95% CI, 0.23-2.27).

CONCLUSIONS The antazoline-based strategy was more effective and safer in comparison with propafenone--based strategy in the pharmacological cardioversion of short-duration AF in our emergency department.

INTRODUCTION Pharmacological cardioversion of short-duration atrial fibrillation (AF) is a common procedure in emergency departments (EDs) around the world.¹ Intravenous administration of class I or III antiarrhythmic drugs or vernakalant is the cornerstone of cardioversion of short--duration AF.^{2.3} Generally, class I antiarrhythmic drugs and vernakalant are the treatment of choice for rapid cardioversion in patients with nonvalvular short-duration AF with significantly better conversion rates than those of amiodarone, of up to 8 hours after administration.^{4,5}

Antazoline is a first-generation antihistaminic agent with "quinidine-like" antiarrhythmic

properties.⁶⁻⁸ Clinically, antazoline is considered to lower the velocity of intraatrial conduction, prolong the atrial refraction period, and improve atrioventricular conduction, allowing a fast ventricular response to supraventricular arrhythmias. In human healthy volunteers, the terminal elimination half-life of antazoline was 2.29 hours with a mean residence time of 3.45 hours and no data on hemodynamic effects of antazoline yet published.⁹ In clinical practice, the drug can be administered intravenously in boluses of 50 to 100 mg every 3 to 5 minutes until successful cardioversion or up to a cumulative dose of 250 to 350 mg.¹⁰⁻¹² While not mentioned in relevant clinical guidelines, published observational studies have suggested high efficacy of antazoline, ranging between 50% and 80% and a rapid onset of action with cardioversion times between 7 and 20 minutes.^{8,10-15} However, there have been no studies examining the comparative effectiveness and safety of antazoline and antiarrhythmic drugs recommended by clinical guidelines.^{2,3}

The aim of the study was to examine the comparative effectiveness and safety of antazoline--based and propafenone-based strategies for a pharmacological cardioversion of short-duration AF in the emergency department of our center.

PATIENTS AND METHODS This was a retrospective case-control study. We searched medical records of the emergency department of a tertiary care cardiac center, covering the years 2008–2012 for all patients who presented with short-duration AF and who underwent pharmacological cardioversion. Data on patients' general characteristics, drugs used, and outcomes of the treatment were collected anonymously. Coronary artery disease (CAD) was defined as a history of stable angina confirmed in a noninvasive or invasive test or a history of acute coronary syndrome or any intervention on coronary arteries. For the purpose of the study, structural heart disease was defined as a history of ischemic cardiomyopathy, nonischemic cardiomyopathy, or significant valvular disease repaired surgically.

Patients were referred for pharmacological cardioversion of short-duration AF according to standard clinical guidelines.² Decisions on drugs used, concomitant treatment, outcome of the cardioversion, and patients' discharge or admission were made by an ED physician on site. The background antiarrhythmic therapy was not discontinued and did not affect the decision of and timing of cardioversion in the ED.

Antazoline was administered intravenously under continuous cardiac monitoring in divided doses of 50 mg every 3 to 5 minutes up to a maximum dose of 250 to 300 mg or conversion to sinus rhythm.^{12,16} Additional intravenous treatment with metoprolol at a dose of 2.5 to 5 mg for rapid ventricular response (ventricular rate >140–150 bpm), saline, potassium, and magnesium was administered at the discretion of the ED physician. Propafenone was administered intravenously in slow bolus under continuous cardiac monitoring. The maximum allowed dose was 2 mg/kg according to relevant guidelines.^{2,3} Again, additional intravenous treatment with metoprolol at a dose of 2.5 to 5 mg, saline, potassium, and magnesium was administered at the discretion of the ED physician.

In cases where the first-line treatment was ineffective (antazoline or propafenone), patients were offered other drugs with different modes of action, referred for electrical cardioversion, or discharged depending on the clinical status and decision of the ED physician. Propafenone had been the only class I antiarrhythmic drug available in Poland, hence the choice of the comparator. Amiodarone was administered in our ED reluctantly due to its slow onset of action.⁵

The primary endpoint of the study was successful cardioversion of AF to sinus rhythm documented on an electrocardiogram. Other endpoints included hospitalization, discharge, reason for hospitalization, and serious adverse events. All endpoints were measured similarly in both groups based on information from official medical records. To minimize the section bias, we included all patients who received at least 1 dose of antazoline or propafenone.

The primary analysis was performed for the comparison of antazoline with propafenone regardless of any additional treatment (β-blocker, magnesium). When data on effectiveness and safety were available, patients administered both drugs (as the first-line or second-line treatment) were included in the analysis in both the treatment and control groups according to the treatment received and documented outcome (eg, if the patient was administered antazoline as the first-line treatment without successful cardioversion and propafenone used as the second--line treatment was effective, for the purpose of the analysis both those outcomes were treated as 2 separate cardioversion attempts). An additional analysis was performed to compare patients receiving exclusively antazoline or propafenone without any additional treatment.

The study was approved by a local ethics committee.

Statistical analysis For the comparison of continuous variables between the study groups, the *t* test was used for normally distributed data (normality of distribution of all continuous variables was explored by examined skewness), and the results were presented as the mean and SD. The comparison of categorical variables between the groups was assessed by the χ^2 test, or the Fisher exact test in cases of a minimum expected count of less than 5, and the results were reported as the absolute numbers and percentages. Relative risk was calculated with 95% confidence interval.

All of the hypotheses were 2-tailed with a 0.05 type I error. The statistical software package SAS

TABLE 1 Basel	ne characteristics of	of study participants
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Parameter	All patients	Antazoline group	Propafenone	P value
		(n = 334)	group	
			(n = 98)	
age, y, mean \pm SD	68.9 ± 9.8	68.8 ± 9.8	69.7 ±9.9	0.4000
sex (male)	280 (64.8)	223 (66.8)	57 (58.25)	0.1168
CAD	166 (38.4)	138 (41.3)	28 (28.6)	0.0226
history of PCI	52 (12.0)	47 (14.1)	5 (5.1)	0.0164
history of CABG	62 (14.3)	53 (15.9)	9 (9.2)	0.0970
history of AF	389 (90.0)	303 (90.7)	86 (87.8)	0.3889
hypertension	257 (59.5)	202 (60.5)	55 (56.1)	0.4398
diabetes mellitus	73 (16.9)	58 (17.4)	15 (15.3%)	0.6324
thyroid disorders	44 (10.2)	29 (8.7)	15 (15.3%)	0.0566
structural heart disease				
none	344 (79.6)	262 (78.4)	82 (83.7)	0.3550
ischemic heart disease	80 (18.5)	66 (19.7)	14 (73.7)	
nonishemic heart disease	3 (0.7)	3 (3.5)	0	
valvular surgery	5 (1.2)	3 (3.5)	2 (10.5)	
cardiac implantable electronic	c device			
none	358 (82.9)	275 (82.3)	83 (84.7)	0.3585
PM	70 (16.2)	56 (16.8)	14 (14.3)	_
ICD	1 (0.2)	0	1 (1.0)	
CRT	3 (0.7)	3 (0.9)	0	
history of concomitant arrhyt	hmia			
AFI	53 (12.3)	40 (12.0)	13 (13.3)	0.7323
AT	13 (3.0)	11 (3.3)	2 (2.0)	0.7412
PVC	16 (3.7)	15 (4.5)	1 (1.0)	0.1356
SSS	93 (21.5)	68 (20.4)	25 (25.5)	0.2753
first-degree AV block	6 (1.4)	6 (1.8)	0	0.3445
second-degree AV block	6 (1.4)	6 (1.8)	0	0.3445
third-degree AV block	2 (0.5)	2 (0.6)	0	1.000
chronic use of antiarrhythmic	drugs			
propafenone	54 (12.5)	32 (9.6)	22 (22.5)	0.0007
amiodarone	16 (3.7)	14 (4.2)	2 (2.0)	0.5421
sotalol	17 (3.9)	15 (4.5)	2 (2.0)	0.3818

Data are presented as number (percentage) of patients unless stated otherwise.

Abbreviations: AF, atrial fibrillation; AFI, atrial flutter; AT, atrial tachycardia; AV, atrioventricular; CABG, coronary artery bypass graft; CAD, coronary artery disease; CRT, cardiac resynchronization therapy; DM, diabetes mellitus; ICD, implantable cardioverter-defibrillator; PCI, percutaneous coronary intervention; PM, pacemaker; PVC, premature ventricular contraction; SSS, sick sinus syndrome

9.2 was used for the analysis (SAS Institute Inc, Cary, North Carolina, United States).

RESULTS In the years 2008–2012, 548 pharmacological cardioversions were performed at our department. Antazoline was administered 334 times and propafenone—98 times; 50 patients converted to sinus rhythm spontaneously without any medication. In 42 cases, antazoline was not effective as the first-line treatment, and patients were given propafenone as the second-line treatment; 2 patients received propafenone as the firstline treatment and antazoline as the secondline treatment. The baseline characteristics of the study group are summarized in TABLE 1. Significantly more patients in the antazoline group had a diagnosis of CAD (41.3% vs 28.6%; P = 0.023), while more patients in the propafenone group used oral propafenone on a daily basis (22.5% vs 9.6%; P = 0007). The mean administered dose of antazoline was 172 ±65 mg (range, 50–350 mg), while all patients received 70 mg (1 vial) of propafenone. Metoprolol was coadministered with antazoline in 247 patients (73.9%) and with propafenone in 27 patients (27.5%) (P < 0.0001).

Primary analysis The primary results are summarized in TABLE 2. In our study, antazoline was

TABLE 2 Clinical outcomes of the antazoline and propafenone groups

Outcome	Antazoline group $(n = 334)^a$	Propafenone group (n = 98)ª	Relative risk (confidence interval)	P value
conversion to sinus rhythm	239 (71.6)	54 (55.1)	1.30 (1.07–1.57)	0.0022
hospital discharge	273 (81.7)	65 (66.3)	1.24 (1.06–1.44)	0.0009
all-cause hospitalization	61 (18.3)	33 (33.7)	0.81 (0.69–0.94)	0.0009
hospitalization for AF	55 (16.5)	26 (26.8)	0.62 (0.41–0.93)	0.0226
hospitalization for AEs	10 (3.0)	4 (4.1)	0.73 (0.23–2.27)	0.5289
hospitalization (other reasons)	5 (1.5)	4 (4.1)	0.36 (0.10–1.33)	0.1209
SBP <100 mmHg	6 (1.8)	4 (4.1)	0.44 (0.13–1.53)	0.2444
bradycardia	32 (9.6)	11 (11.2)	0.85 (0.45–1.63)	0.6327

Data are presented as number (percentage) of patients.

a Discharge and hospitalization rates do not sum up to 100% owing to the possibility of more than 1 indication for hospitalization.

Abbreviations: AE, adverse events; SBP, systolic blood pressure; others, see TABLE 1

 TABLE 3
 Clinical outcomes in the subgroup of patients who received exclusively antazoline or propatenone without any concomitant medications

Outcome	Antazoline group $(n = 41)^{a}$	Propafenone group $(n = 55)^a$	Relative risk (confidence interval)	P value
conversion to sinus rhythm	32 (78.0)	26 (47.3)	1.65 (1.20–2.28)	0.0023
hospital discharge	32 (78.)	34 (61.8)	1.26 (0.97–1.64)	0.0897
all-cause hospitalization	9 (22.0)	21 (38.2)	0.79 (0.61–1.03)	0.0897
hospitalization for AF	5 (12.2)	17 (31.5)	0.39 (0.16–0.96)	0.0273
hospitalization for AEs	2 (4.9)	2 (3.7)	1.32 (0.19–8.96)	1.0000
hospitalization (other)	0 (0)	2 (3.7)	not available	0.5041
SBP <100 mmHg	1 (2.4)	1 (1.8)	1.34 (0.09–20.8)	1.0000
bradycardia	7 (17.1)	7 (12.7)	1.34 (0.51–3.53)	0.5507

Data are presented as number (percentage) of patients.

a Discharge and hospitalization rates do not sum up to 100% owing to the possibility of more than 1 indication for hospitalization.

Abbreviations: see TABLES 1 and 2

more effective than propafenone in pharmacological cardioversion of short-duration AF: 71.6% vs 55.1% (RR, 1.3; 95% CI, 1.07–1.57; P = 0.002). This translated directly to lower rates of hospitalization and better discharge rates. The main indication for hospitalization was ineffective pharmacological cardioversion of poorly tolerated AF, while complication rates were low and comparable between treatments.

Additional analysis In an additional analysis, we compared antazoline and propafenone administered alone without any concomitant medical treatment in the ED. The baseline characteristics of patients in this subgroup are summarized in TABLE 3. The mean administered dose of antazoline was 148 ±56 mg (range, 50–300 mg), while all patients received 70 mg (1 vial) of propafenone. The results were similar to those of the primary analysis, with better effectiveness of antazoline and less hospitalizations in this subgroup (TABLE 3).

DISCUSSION To our knowledge, this is the first study describing the real-world comparative effectiveness and safety of antazoline, a first generation antihistaminic agent with antiarrhythmic properties, and of propafenone, a class I antiarrhythmic drug recommended by clinical guidelines. In some European countries, propafenone is the only available class I antiarrhythmic drug, and amiodarone was not considered a proper comparator in this study due to the slow onset of action.^{2–5}

The observed effectiveness of antazoline (a 71.6% success in pharmacological cardioversion of short-duration AF to sinus rhythm) was similar to the effectiveness reported in previous publications.^{8,10-15} Antazoline was administered intravenously in boluses of 50 to 100 mg every 3 to 5 minutes up to a maximal cumulative dose of 350 mg or conversion to sinus rhythm. Higher doses were not administered due to a marginal gain in effectiveness and significantly higher rates of adverse events described earlier.^{12,15} About 73.9% of the patients received intravenously a concomitant β -blocker, metoprolol (2.5–5 mg), as described in the available literature.^{12,15} Also, physicians used intravenous saline, potassium, or magnesium.

The effectiveness of propafenone in this study (55.1%) was consistent with the results of other published studies.^{4,5} However, the administration of propafenone in this study deviated from the regimen recommended in clinical guidelines: all patients were treated with a single slow bolus of 70 mg (1 vial) without any additional boluses or infusions of the drug, while guidelines suggest doses of up to 2 mg/kg of body mass.^{2,3} Similarly to the antazoline group, intravenous β -blocker, saline, potassium, and magnesium were administered during the cardioversion.

Generally, in our center, antazoline was the drug of choice (334 vs 98 patients) in a wide range of patients with short-duration AF: about 60% of the patients had a history of hypertension, 40% had documented CAD, 22% had some sort of structural heart disease (including 5 patients with valvular disease treated surgically), and 18% had a cardiac implantable electronic device. The antazoline-based pharmacological cardioversion was marginally but significantly superior to the propafenone-based approach (RR, 1.30; 95% CI, 1.07–1.57), with lower rates of hospital admission and higher rates of discharge (TABLE 2). The additional analysis preformed in patients who received exclusively antazoline or propafenone without any concomitant treatment revealed similar results to the primary analysis (TABLE 3). These results warrant a randomized controlled trial to confirm our findings.

Hospitalizations in both groups were driven mainly by unsuccessful pharmacological cardioversion and therefore were significantly less common in the antazoline group. Only a marginal percent of admissions was due to the adverse effects of the treatment: mainly sinus bradycardia or mild hypotension (TABLE 2). Some other indications for hospitalization were lone cases of dizziness, nausea, chest discomfort or clinical suspicion of CAD, and episodes of atrial flutter/tachycardia after cardioversion. Well-known mild adverse effects of antazoline such as hot flush, metallic taste, or drowsiness were not consistently reported in medical documentation and therefore were not analyzed in this study.^{8,10,12,15}

An interesting finding of the study was a relatively high proportion of patients with documented CAD or structural heart disease in the antazoline group (TABLE 1). Propafenone had been administered more reluctantly in those patients, which is understandable in the light of clinical guidelines.^{2,3} Patients with structural heart disease were included or excluded from the previous antazoline studies depending on the publication: for instance, structural heart disease was an exclusion criterion in the AnPAF trial.^{8,10,12,16} The general effectiveness and safety of antazoline in those groups of patients remain unclear and warrant further research. **Limitations** This was a retrospective case-control study and all limitations of this methodology apply to the study. A selection bias was highly probable, with significantly more patients taking propafenone on a daily basis being treated with propafenone in the ED. In an attempt to limit this bias, we included all patients who received at least 1 dose of any of the studied drugs.

One of the main limitations of our study was the fixed dose of propafenone used in all patients regardless of the body mass, which most likely led to a suboptimal dosing in most cases and lowered the overall effectiveness of the propafenone-based strategy, thus altering the results of the analysis.

Due to the retrospective character of the study, not all data of interest were available. For example, the exact time to conversion after the treatment and exact time of stay in the ED were generally not included in the medical documentation and could not be analyzed. Antazoline was reported to have a rapid onset of action and times to conversion ranging between 7 and 20 minutes, while the effectiveness of propafenone might improve with time.^{4,5,10-12} To set the study within a time perspective, the average time of stay among 199 patients with AF treated in our ED in 2015 was 180.5 \pm 105.2 minutes (range, 10–627 minutes); median, 161 minutes (IQR, 110; 235].

Source documentation also lacked data on mild or temporary adverse effects of both treatments. On the other hand, data on serious adverse events or situations that lead to hospitalizations were meticulously reported and therefore analyzed in this study.

This was an analysis of real-world clinical data derived from medical records archived in our center, hence the choice of the drug administered, variations in a dose regimen, and administration of cotreatment did not strictly follow the widely recognized clinical guidelines but still represented the clinical practice.^{2,3} This is not unusual as published studies suggest a high variation in antiarrhythmic drug usage and high proportion of non-guideline treatments in paroxysmal and persistent AF.^{17,18}

Conclusions Antazoline-based strategy was effective and safe in comparison with propafenone-based strategy in a pharmacological cardioversion of short-duration AF in our ED in a wide range of patients.

Contribution statement MMF and AM conceived the idea and designed the study. All authors were involved in data collection and interpretation of the results. IK performed the statistical analysis. MMF prepared the draft manuscript. All authors edited and approved the final version of the manuscript. HS supervised the study.

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ARTYKUŁ ORYGINALNY

Analiza porównawcza efektywności i bezpieczeństwa strategii opartej na antazolinie lub propafenonie w kardiowersji farmakologicznej krótkotrwałego migotania przedsionków w izbie przyjęć

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SŁOWA KLUCZOWE STRESZCZENIE

antazolina, efektywność porównawcza, kardiowersja farmakologiczna, migotanie przedsionków, propafenon

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WPROWADZENIE Liczne doniesienia opisywały efektywność antazoliny stosowanej w kardiowersji farmakologicznej krótkotrwałego migotania przedsionków (*atrial fibrillation* – AF). Brakuje jednak danych na temat porównania antazoliny z lekami antyarytmicznymi wymienianymi w wytycznych klinicznych. CELE Celem badania była analiza porównawcza efektywności i bezpieczeństwa strategii opartej na antazolinie lub propafenonie w kardiowersji farmakologicznej krótkotrwałego AF wykonywanej w warunkach izby przyjęć.

PACJENCI I METODY Przeprowadzono retrospektywne badanie kliniczno-kontrolne oparte o analizę dokumentacji medycznej pacjentów poddawanych kardiowersji farmakologicznej krótkotrwałego AF za pomocą antazoliny lub propafenonu podawanych dożylnie w naszej izbie przyjęć w latach 2008–2012. Pierwszorzędowym punktem końcowym analizy była skuteczna kardiowersja AF. Pierwszorzędowym punktem końcowym dotyczącym bezpieczeństwa była hospitalizacja z powodu powikłań zastosowanego leczenia. **WYNIKI** Przeanalizowano 432 przypadki kardiowersji. Średni wiek pacjentów wynosił 68,9 ± 9,8 roku; 65% pacjentów stanowili mężczyźni; 90% miało AF w wywiadzie. Antazolinę zastosowano 334 razy, a propafenon – 98 razy. Średnia dawka antazoliny wynosiła 172 ± 65 mg, podczas gdy wszyscy pacjenci w grupie propafenonu otrzymali lek w stałej dawce 70 mg (jedna fiolka). Kardiowersja za pomocą antazoliny była skuteczna w 239 przypadkach (71,6%), a propafenonu w 54 przypadkach (55,1%) (RR 1,30; 95% CI: 1,07–1,57). Odsetek hospitalizacji z powodu efektów niepożądanych leczenia był niski i podobny w obu badanych grupach: 10 (3,0%) w przypadku antazoliny oraz 4 (4,1%) w przypadku propafenonu (RR 0,73; 95% CI: 0,23–2,27).

WNIOSKI Strategia oparta na antazolinie była skuteczniejsza i bezpieczniejsza w porównaniu ze strategią opartą na propafenonie w kardiowersji farmakologicznej krótkotrwałego AF przeprowadzanej w warunkach naszej izby przyjęć.