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A systematic review of the effectiveness of catheter ablation NavX mapping system for treatment of the cardiac arrhythmia

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Abstract

Background: Catheter ablation is widely used for treatment of atrial fibrillation. The use of fluoroscopic and non-fluoroscopic mapping systems in catheter ablation is common. This study conducted to investigate the safety and effectiveness of Navx non-fluoroscopic mapping system.

Methods: In this study, the appropriate electronic databases including Cochrane Library and Ovid Medline searched until August 2013 using free text and MeSH. Systematic reviews, health technology assessment reports in which systematic review was conducted and controlled trials with the sample size of 100 patients and more were included into the study. Results of included studies were analyzed qualitatively.

Results: Seven papers were included in this study. According to these studies, non-fluoroscopic guidance systems may reduce the exposure to radiation compared to fluoroscopic system. NavX system has minimum exposure time. Non-fluoroscopic guidance systems are safer than fluoroscopic guidance system. NavX system reduces the procedure and fluoroscopy time. There was no significant difference between two systems, NavX and Carto, based on their safety and effectiveness.

Conclusion: Ensite NavX system is relatively safer and more effective than fluoroscopic guidance systems for treating the cardiac arrhythmia.

Keywords: Catheter Ablation, Cardiac Arrhythmia, Systematic Review.

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Introduction

Atrial fibrillation is one of the most prevalent cardiac arrhythmia with high rate of morbidity and mortality. These conditions are determined by rapid and irregular activities of both cardiac atriums accompanying with irregular response of both ventricles. Heartbeat is usually between 120 to 160 times per minute, in some patients, this might be increased to 200 beats per minute. Patients affected by atrial fibrillation are at higher risk of clot formation followed by homodynamic occurrences such as infarction. Atrial fibrillation may increase the infarction risk up to 4 to 5 times in all age groups resulting in 10 to 15% increase in all ischemic infarctions. This type of arrhythmia is the most prevalent cause of all infarctions among elderly people resulting in 25% of infarctions among elderly patients with age more than 80 (1). Treatment methods used for treatment of the atrial fibrillation may include medical methods for preventing the heart failure, medical procedures for controlling the heartbeat and car-

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dioversion, in this case, a controlled electric shock is administered to the heart to return it to its normal rhythm. Catheter Ablation, that is used for preventing the occurrence of atrial fibrillation and using a pace maker for normalizing the heartbeat (2). Catheter Ablation is a percutaneous procedure in which energy is transferred by a thin flexible wire (catheter) to eradicate the abnormal cardiac tissue responsible for arrhythmia. Catheter Ablation is directed towards cardiac together with a mapping catheter and pacemaker catheter by groin vein. Energy is transferred by catheter towards cardiac tissue to eradicate the tissues making arrhythmia. Radiofrequency energy is the most common type of energy used in Catheter Ablation (3). One of the traditional methods for administrating the catheter is using fluoroscopy; although Ablation administered by this method might come with successes for ending the continuous arrhythmia with predictable anatomic situations, however, this method is less successful for administrating the ablation for treating the advanced arrhythmia such as atrial fibrillation (3). Recently, advanced non-fluoroscopic mapping systems are used for properly administrating the ablation in catheter ablation. This advanced system includes four types: (a) CARTO EP: includes weak magnetic fields. In this method, a magnetic sensor is used together with a destructive catheter for determining the situation of catheter; thus it makes a 3D geometry of cardiac; (b) EnSite System: it includes non-contact multi-electrode catheter making a simultaneous mapping; processing unit uses electric data to calculate more than 3000 isopotential electrogram, by which, it makes a 3D map from heart; (c) The LocalLisa Intracardiac System: it includes an electric field for determining the situation of mapping catheter; in this method, the situation of electrodes is formed in 3D virtual space in mapping catheter; thus, catheter can detect the abnormal electric potential destructor; (d) Polar Constellation Advanced Mapping Catheter System: it includes multi-electrode catheter with 64 electrodes in 8 rows. By this catheter, an accurate electric map from atrium in several heartbeats is obtained (3). EnSite NavX is one of the non-fluoroscopic systems. This study has been conducted to investigate the safety and effectiveness of this non-fluoroscopic mapping system to provide the policy maker with proper decisions in this field.

Methods

Available electronic databases including Cochrane Library and Ovid Medline were searched until August 2013 to find related papers without language restrictions. Two separate search strategies including free text and MeSH were used. Although all papers found had English abstract, non-English papers were removed from the study. Sixteen papers were retrieved from Cochrane Library and 202 papers from Ovid Medline using the following search strategies (in Box A and B).

Duplicate and unrelated papers were removed from the study and 33 papers were remained. The full text of obtained papers was investigated based on inclusion/exclusion criteria determined by authors. Based on inclusion criteria, 7 papers included in final phase (Fig. 1, Tables 1 & 2). Included papers were independently checked by two reviewers using a structured form for data extraction. Data were collected by a reviewer and controlled by a second reviewer. Inclusion criteria in this study were the population of patients affected by cardiac arrhythmia who treated

A) Search strategy for Cochrane Library
#1) "Electrophysiologic Mapping Systems"
#2) MeSH Descriptor "Electrophysiologic Mapping Systems" explode all trees
#3) Ensite
#4) NavX
#5) (#1 or #2 or #3 or #4)

B) Search strategy for Ovid -Medline
#1) "Electrophysiologic Mapping Systems".mp.
#2) Ensite.mp.
#3) NavX.mp.
#4) (#1 or #2 or #3 or #4)

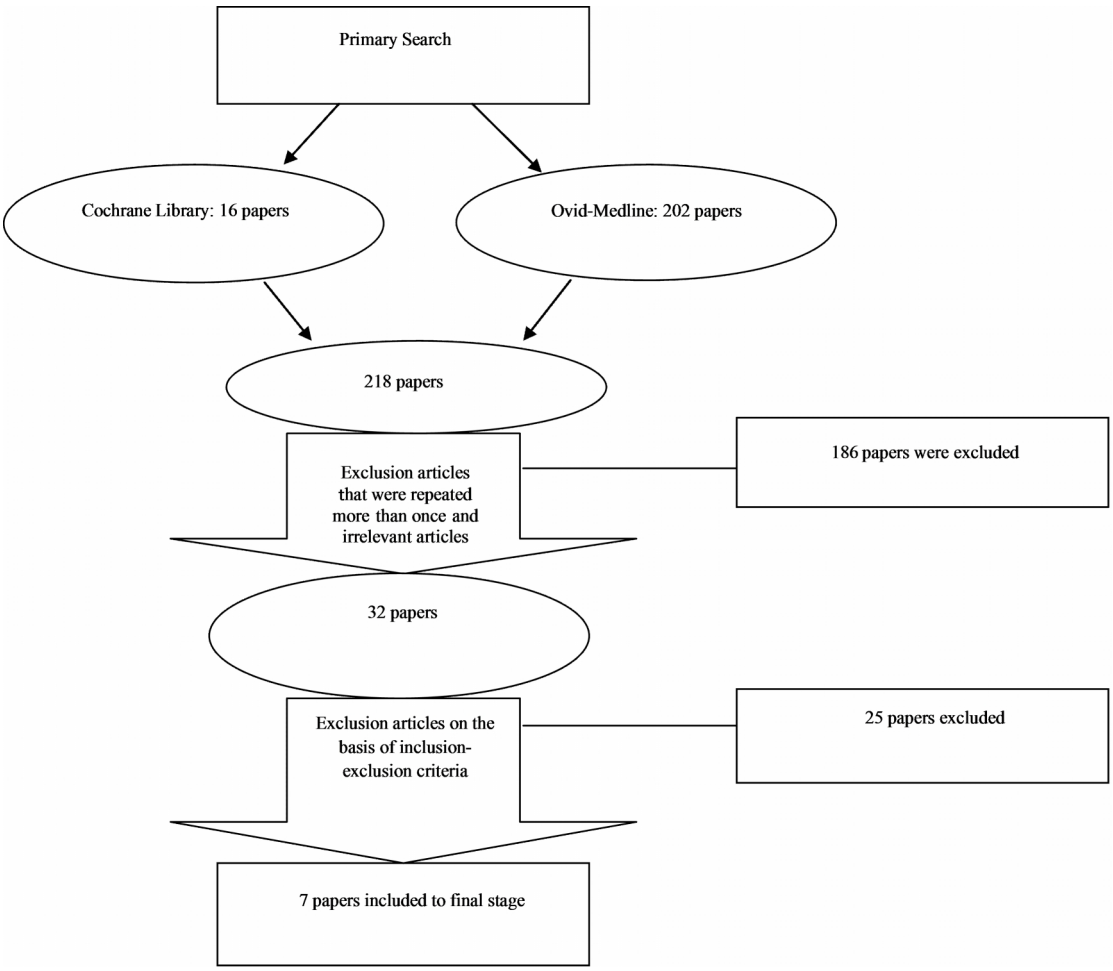

Fig. 1. Flow of papers through the study

by catheter ablation using advanced non-fluoroscopic mapping system (Ensite NavX). Patients were selected based on outcomes (such as success rate of treatment), radiation dose, total intervention time and rate of disorders from interventions (such as infarction compared with other common mapping methods including fluoroscopy and or other non-fluoroscopy systems). The included studies were selected based on high levels of evidence using medicine pyramid, namely, systematic reviews and health technology assessment reports in which the systematic reviews conducted as well as controlled trials with the sample size of 100 subjects and more. The studies conducted on the population of healthy people, animal, phantom and cadaver were excluded from this study. Although most studies included in this study had good quality, however, the quality of studies weren't used for exclusion of the papers. Results of included studies are analyzed qualitatively by thematic synthesis.

Results

From seven papers included in final phase, one paper was health technology assessment (3); two were retrospective controlled clinical trials (5, 8); one was controlled clinical trial (7); one was randomized controlled trial (9); one was retrospective randomized controlled trial (6) and one was prospective randomized controlled trial (4). Of these studies, three papers conducted on 2012 (5, 9, 8); two on 2011 (6, 7); two on 2006 (3, 4). Sample size in the included studies was between 100 to 388 patients (Table 1). Results from included studies were qualitatively analyzed by thematic synthesis in two sub-categories including safety and effectiveness.

Table 1.The List of Included Studies

Author, Publication Date	Sample size	Paper Title	Study Type
Health Quality Ontario.2006	-	Advanced electrophysiologic mapping systems: an evidence-based analysis (3)	Health Technology Assessment(Systematic Review + Economic Evaluation)
Earley MJ et al.2006	145	Radiofrequency ablation of arrhythmias guided by non-fluoroscopic catheter location: a prospective randomized trial(4)	Prospective Randomized Controlled Trial
Tuzcu V. 2012	305	Significant reduction of fluoroscopy in pediatric catheter ablation procedures: long-term experience from a single center(5)	Retrospective Controlled Clinical Trial
Choo WK et al.2011	109	Experience of atrial fibrillation ablation in a new cardiac centre using three-dimensional mapping and multielectrode duty-cycled radiofrequency ablation(6)	Retrospective Randomized Controlled Trial
Jilek C et al. 2011	100	Visualization of multiple catheters in left atrial ablation procedures: Comparison of two different 3D mapping systems(7)	Controlled Clinical Trial
Kwong W et al.2012	338	The effect of NavX on fluoroscopy times in pediatric catheter ablation(8)	Retrospective Controlled Clinical Trial
Casella M. et al.2012	210	Rationale and design of the NO-PARTY trial: near-zero fluoroscopic exposure during catheter ablation of supraventricular arrhythmias in young patients (9)	Randomized Controlled Trial

1- Safety

Results obtained for safety aspect of this technology were analyzed and categorized in three sub-classes including radiation dose, complications and radiation duration (Table 3).

1-1- Radiation Dose

Fluoroscopy time and radiation dose was considerably low in Carto and NavX group comparing to conventional mapping group. In addition, the lowest fluoroscopy time and exposure to radiation in NavX group was significantly lower than Carto group. X-ray wasn't used during this procedure in 27% of NavX cases. For common atrial flutter using conventional fluoroscopy mapping, the risk of affecting by disorder was 1 per 6600; however, this risk could be reduced to a half by using NavX (4).

1-2- Complications

The rate of complications in ablation of pulmonary venous that is conducted by a guidance system during a follow-up period of 6 to 29 months is 0 to 10% with median of 6%. Rate of complications with the longest follow-up period (28 month) was 8%. The most common advanced guided catheter ablation complications included infarction, transient ischemic attack, cardiac tamponade, myocardium infarction, atrial flutter, congestive heart failure, pulmonary venous congestion (3). Fluoroscopy could be significantly reduced and or even removed in most catheter ablation procedures. Long term results approved that this could be conducted more efficient and safer (5). Non-fluoroscopic guidance systems come with disorders from 1 to 40% (median 25%) during 3 to 19 month resulting in 10% relative reduction in total disorder for advanced guided ablation comparing to ablation guided with fluoroscopy for treatment of the atrial fibrillation (3). There was no significant difference in the rate of complications between groups, 3D mapping (NavX and Carto) and Pulmonary Vein Ablation Catheter (PVAC) (p=0.61). No complication resulted in death and there wasn't any mortality resulted from arrhythmia during the 6 month follow-up (6).

1-3- Radiation Duration

Advanced non-fluoroscopic guidance systems seemed to be safe. In addition, studies indicated that they continuously reduce the

Table 2. Excluded papers and exclusion reasons

Code	Paper Title	Exclusion Reason
1	Ablation of atrial fibrillation using novel 4-dimensional catheter tracking within autoregistered left atrial angiograms.	The sample size was less than the amount specified in the inclusion criteria.
2	A randomised comparison of Cartomerge vs. NavX fusion in the catheter ablation of atrial fibrillation: the CAVERN Trial.	The sample size was less than the amount specified in the inclusion criteria.
3	"Near-zero" fluoroscopic exposure in supraventricular arrhythmia ablation using the EnSite NavXTM mapping system: personal experience and review of the literature.	The sample size was less than the amount specified in the inclusion criteria.
4	CARTO-guided vs. NavX-guided pulmonary vein antrum isolation and pulmonary vein antrum isolation performed without 3-D mapping: effect of the 3-D mapping system on procedure duration and fluoroscopy time	The sample size was less than the amount specified in the inclusion criteria.
5	Improved electrogram attenuation during ablation of paroxysmal atrial fibrillation with the Hansen robotic system.	No one of the inclusion criteria was met.
6	Nonfluoroscopic imaging systems reduce radiation exposure in children undergoing ablation of supraventricular tachycardia.	The sample size was less than the amount specified in the inclusion criteria.
7	Right ventricular substrate mapping using the Ensite Navx system: Accuracy of high-density voltage map obtained by automatic point acquisition during geometry reconstruction.	The sample size was less than the amount specified in the inclusion criteria.
8	Pulmonary vein isolation and left atrial catheter ablation using a three-dimensional navigation system for the treatment of atrial fibrillation.	The sample size was less than the amount specified in the inclusion criteria.
9	Catheter ablation of atrial fibrillation using the Navx-/Ensite-system and a CT-/MRI-guided approach.	The sample size was less than the amount specified in the inclusion criteria.
10	Pulmonary vein isolation and left atrial catheter ablation using a three-dimensional navigation system for the treatment of atrial fibrillation.	The sample size was less than the amount specified in the inclusion criteria.
11	EnSite Velocity cardiac mapping system: a new platform for 3D mapping of cardiac arrhythmias.	A review study, Study Type was not based on inclusion criteria
12	Image integration using NavX Fusion: initial experience and validation.	The sample size was less than the amount specified in the inclusion criteria.
13	Is it possible to perform a linear lesion with no local electrograms using a three-dimensional mapping system for the ablation of typical atrial flutter?	The sample size was less than the amount specified in the inclusion criteria.
14	Is it possible to create a linear lesion with no local electrograms? Comparison between a three-dimensional mapping system and conventional fluoroscopy for cavotricuspid isthmus ablation of typical atrial flutter.	The sample size was less than the amount specified in the inclusion criteria.
15	A NavX-guided ablation of a nodo-fascicular fibre.	A case study, Study Type was not based on inclusion criteria.
16	A nonfluoroscopic approach for electrophysiology and catheter ablation procedures using a three-dimensional navigation system.	The sample size was less than the amount specified in the inclusion criteria.
17	Elimination of fluoroscopy use in a pediatric electrophysiology laboratory utilizing three-dimensional mapping.	The sample size was less than the amount specified in the inclusion criteria.
18	Advanced mapping techniques in atrial fibrillation.	A review study, Study Type was not based on inclusion criteria.
19	Nonfluoroscopic catheter navigation for radiofrequency catheter ablation of supraventricular tachycardia in children.	The sample size was less than the amount specified in the inclusion criteria.
20	Electrical isolation of pulmonary veins in patients with atrial fibrillation: reduction of fluoroscopy exposure and procedure duration by the use of a non-fluoroscopic navigation system (NavX).	The sample size was less than the amount specified in the inclusion criteria.
21	Real-time, three-dimensional localization of a Brockenbrough needle during transseptal catheterization using a nonfluoroscopic mapping system.	No one of the inclusion criteria was met.
22	Electroanatomical systems to guided circumferential pulmonary veins ablation for atrial fibrillation: initial experience from comparison between the Ensite/NavX and CARTO system.	The sample size was less than the amount specified in the inclusion criteria.
23	Catheter ablation of common-type atrial flutter guided by three-dimensional right atrial geometry reconstruction and catheter tracking using cutaneous patches: a randomized prospective study.	The sample size was less than the amount specified in the inclusion criteria.
24	Catheter ablation of common-type atrial flutter guided by three-dimensional right atrial geometry reconstruction and catheter tracking using cutaneous patches: a randomized prospective study.	The sample size was less than the amount specified in the inclusion criteria.
25	Atrial fibrillation ablation.	No one of the inclusion criteria was met.

time of fluoroscopy and exposing to radioactivity (3). NarvX results in minimum exposure to x-ray (NavX vs. conventional fluoroscopy, averagely 4 min comparing to 13 min ($p<0.001$)). (NavX vs. Carto, averagely 4 min comparing to 6 min ($p<0.0008$)) (4). In the Carto 3 group comparing to NavX group, the average duration of x-ray was 40±21min against 40±18 per min) ($p=0.982$) (7).

2- Effectiveness

Results obtained for effectiveness were analyzed and categorized in eight subclasses including procedure time, acute success rate, patient survival, recurrence,

Table 3. Safety outcomes used in the included studies

Author, Publication Date	Intervention	Sample Size		Complications		Radiation dose (Gy/ cm^2)	Radiation duration (min)
		N	%	Type	N		
Choo et al, 2011	PVAC	38	35	Pericardial Effusion, Periprocedure Stroke	2	-	-
	NavX	24	22	Pulmonary Vein Puncture	1	-	-
	Carto	47	43	PericardialTamponade	1	-	-
Earley et al, 2006	Carto	49	-	-	1	5(1-89)*	6(1-55) *
	NavX	45	-	-	1	2(0-54) *	4(0-50) *
	Conventional mapping	51	-	-	0	12(1-106) *	13(2-46) *
Jilek et al, 2011	Carto3	50	-	Mild Asymptomatic Stenosis	1	34±17**	40±21**
	NavX	50	-	Mild Asymptomatic Stenosis	1	39±22**	40±18**
Health Quality Ontario,2006	Three dimensional mapping systems(Carto& NavX)	-	-	Stroke, transient ischemic attack, cardiac tamponade, myocardial infarction, atrial flutter, congestive heart failure, and pulmonary vein stenosis.	46/589(8%) during a follow-up period of 28 months	-	-

*Median(range)

**Mean±SD

relief from arrhythmia index, arrhythmia load and needing for anti-arrhythmia drugs and visual representation (Table 4).

2-1- Procedure Time

Based on the outcome of intervention time, this rate is 166.6±56.1 for NavX individually and 202.8±83.1 for both NavX and Fluoroscopy simultaneously (5). For common atrial flutter, Carto and NavX reduce the screening time without increased cost of procedure (4). There was no significant difference between mean procedure duration for Carto 3 comparing to control group (NavX) (205±83 comparing to 189±72 min (p=0.174)) (7). Based on general intervention time, ablation of PVAC was considerably quicker than 3D ablation mapping (168 min comparing to 252 min, p<0.0001); in average, it lasts 159 min for paroxysmal Atrial Fibrillation and 206 min for Persistent Atrial Fibrillation. Based on the lower intervention duration, in PVAC, fluoroscopy is conducted faster (39 minutes comparing to more than 70 minutes for 3D mapping; p<0.0001) (6). NavX mapping technology considerably reduces the fluoroscopy ablation time (159±14.3 comparing to 11±8.9 min for NavX; p<0.01) and also it reduces total duration for fluoroscopy (26.4±15.6 comparing to 23.8±11.1 min for NavX; p=0.95). Total procedure time had no significant difference in both technologies (210.1±66 comparing to 222.8±61 for NavX; p=0.13) (8).

2-2- Acute Success Rate

For non-fluoroscopic guidance systems, the acute success rate is between 69% and 100% that isn't significantly different from ablation by fluoroscopy (3). For acute success rate, this is 97.8% for NavX individually and 94% for both NavX and fluoroscopy (5). The acute success rate for three methods, Carto, NavX and PVAC were 96%, 100% and 97% respectively (p<0.42). The acute success rate for paroxysmal atrial fibrillation and persistent atrial fibrillation

Table 4. Effectiveness outcomes used in the included studies

Author, Publication Date	Sample Size	Interven-tion	Procedural Duration			Acute Success rate (%)	Overall Success rate (%)	Free-dom from index Arrhyth-rhyth-mia (%)	Freedom from Symp-toms (%)	Recur cur-rence rate (%)
			Fluorosco-py ablation time (min)	Fluoroscopy time (min)	Overall Procedure time (min)					
Choo et al, 2011	109	PVAC	-	(39 ± 14)**	(168 ± 41)**	97	68	-	-	-
		NavX	-	(79 ± 25)**	(265 ± 60)**	100	38	-	-	-
		Carto	-	(73 ± 27)**	(246 ± 60)**	96	40	-	-	-
Kwong W et al.2012	338	NavX	(11±8.9)**	(24±11.1)**	(223±61)**	95.90	-	-	-	-
		Conven-tional mapping	(16±14.3)**	(26±15.6)**	(210±66)**	95.70	-	-	-	-
Earley et al, 2006	145	Carto	-	-	90 (30–180)*	98	-	88	86	-
		NavX	-	-	90 (45–200)*	98	-	87	87	-
		Conven-tional mapping	-	-	90 (25–180)*	100	-	86	92	-
Jilek et al, 2011	100	Carto3	-	-	(205±83)**	-	-	-	-	-
		NavX	-	-	(189±72)**	-	-	-	-	-
Tuzcu V, 2012	305	Single NavX	-	-	(167±56.1)**	-	-	-	-	10.20
		NavX + Fluorosco-py	-	-	(203±83.1)**	-	-	-	-	10
Weighted Mean	Pooled Sample 997	NavX	-	-	-	97.17	-	-	-	-
Health Quality Ontario, 2006 (systematic review)	-	3D map-ping sys-tems(Carto & NavX)	-	-	-	69-100	-	79	-	-

*Median (range)
**Mean±SD

were 100% and 92% respectively (p=0.03). Most patients with paroxysmal atrial fibrillation comparing to permanent atrial fibrillation remained also in sinus rhythm for 6 months (59% comparing to 31%; p=0.005) (6). There was no difference between acute successes of ablation in common treatment group and NavX group; on the other hand, general success rate was similar for both technologies (95.7% and 95.9% respectively) (8).

2-3- Success Rate

In evaluation of 6 month success rate, there was no significant difference between Carto and NavX technologies (40% comparing to 38%; p=0.81). However, PVAC group obtained more success comparing the combination of both 3D mapping groups (68% comparing to 39%; p=0.004). Studying the response rate of different types of atrial fibrillation after each ablation method indicated that the 6 month success rate in patients affected by paroxysmal atrial fibrillation was considerably higher in PVAC than 3D mapping technologies (73% comparing to 49%; p=0.04); however there was no significant difference in such technologies in patients affected by permanent atrial fibrillation (6).

2-4- Patient Survival

Circumferential PV Ablation using a non-fluoroscopic system results in improved survival of patient during 28 months after treatment comparing to medications (3).

2-5- Recurrence rate

Recurrence rate was 10.2% for Navx individually and 10% for both NavX and fluoroscopy simultaneously (5).

2-6- Freedom from Arrhythmia Index

Circumferential PV Ablation using a non-fluoroscopic system results in elimination of the atrial fibrillation (with or without

anti-arrhythmia drugs) in 75% to 95% of patients (median= 79%). This effect may be maintained up to 28 months. Elimination of the atrial fibrillation without arrhythmic drugs were detected in 47% to 95% of patients (median= 63%) (3).

2-7- Arrhythmia Load and Needing for Anti-Arrhythmic drugs

Advanced guidance systems indicated that arrhythmic load has reduced the need for anti-arrhythmic medicines in patients with advanced arrhythmia whom the guided ablation by fluoroscopy wasn't effective (3).

2-8- Visual Presentation

Advanced non-fluoroscopic guidance systems provide 3D images in real time by integrating the potential electric and anatomic information and this may improve the visual presentation of points considered for ablation (3).

Discussion

According to studies, it could be stated that non-fluoroscopic guidance systems reduce the exposure rate to radiation comparing to the fluoroscopy system; among them, NavX system has lower exposure than Carto (4). It could also be stated that despites presence of complications such as infarction, transient ischemic attack, cardiac tamponade, myocardial infarction, atrial flutter, congestive heart failure and PV congestion, non-fluoroscopic guidance systems are safer than fluoroscopic guidance systems; however, there is no significant difference between both systems, NavX and Carto (3, 6). NavX system generally reduces the procedure and fluoroscopy time; there is no significant difference between Carto and this system (4-8). Regrading acute success rate, there is no significant difference between non-fluoroscopic guidance systems and conventional fluoroscopic systems (3). Conducting catheter ablation procedure using non-fluoroscopic system by integrating the potential electric and anatomic information may effectively eliminate the atrial fibrillation; these systems can reduce the arrhythmic load and need for anti-arrhythmic medicines in patients with advanced arrhythmia in whom the fluoroscopy-guided ablation wasn't effective (3). According to present evidences, non-fluoroscopic guidance systems (NavX and Carto) are relatively safer and more effective methods than fluoroscopic guidance systems for treating the cardiac arrhythmia. It must be also noted that there is no difference between NavX and Carto systems in terms of safety and effectiveness.

Conclusion

Ensite NavX system is relatively safer and more effective than fluoroscopic guidance systems for treating the cardiac arrhythmia.

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Conflict of Interest

The authors have no conflict of interest in this article.

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