ORIGINAL ARTICLE

Is the systematic use of mapping systems during His Bundle catheter ablation cost-effective? A single-center experience

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Abstract

Aim: Three-dimensional (3D) nonfluoroscopic mapping systems (NMSs) are generally used during the catheter ablation (CA) of complex arrhythmias. We evaluated the efficacy, safety, and economic advantages of using NMSs during His-Bundle CA (HB-CA). **Methods:** A total of 124 consecutive patients underwent HB-CA between 2012 and 2019 in our EP Laboratory. We compared two groups: 63 patients who underwent HB-CA with fluoroscopy alone from 2012 to 2015 (Group I) and 61 patients who underwent HB-CA with the aid of NMSs from 2016 to 2019 (Group II). Two cost-effectiveness analyses were carried out: the alpha value (AV) (ie, a monetary reference value of the units of exposure avoided, expressed as \$/man Sievert) and the value of a statistical life (VSL) (ie, the amount of money that a community would be willing to pay to reduce the risk of a person's death owing to exposure to radiation, it is not the cost value of a person's life). The cost reduction estimated by means of both these methods was compared with the real additional cost of using NMSs.

Results: The use of NMS resulted in reduced fluoroscopy time in Group II {median 1.35 min} in comparison with Group I {median 4.8 min (P < .05)}. The effective dose reduction (ΔE) was 1.16 milli-Sievert.

Conclusion: The use of NMS significantly reduces fluoroscopy time. However, the actual reduction is modest and in our EP Laboratory this reduction is not cost-effective. Indeed, when the ΔE is referred to country and agency tables for absolute values of AV or VLS, it is not economically advantageous in almost all cases.

KEYWORDS

cost-effectiveness, electroanatomic mapping system, electrophysiological procedures, His-Bundle catheter ablation

1 | INTRODUCTION

His-bundle catheter ablation (HB-CA) and the implantation of a pacemaker is a well-established rate control therapy in atrial fibrillation (AF) when medications fail to control ventricular rate (Ablate and Pace Strategy). This type of procedure is relatively simple and fast, and has a low complication rate. The ESC 2016 guidelines assign a Class IIa (B) indication for HB-CA in this type of AF patient.¹

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Radiofrequency is the most commonly used energy source in catheter ablations in general, and fluoroscopy is used for catheter placement. However, exposure to radiation increases the lifetime risk of malignancies and genetic defects in patients and operators.²

In the last 20 years, several studies have shown that the use of three-dimensional (3D) nonfluoroscopic mapping systems (NMSs) during catheter ablation (CA) is safe and effective for the treatment of complex and simple arrhythmias in children and adults. In addition, their use permits a significant reduction in X-Ray exposure.³⁻⁷

In our previous papers, we reported that the systematic use of NMSs could dramatically reduce X-Ray exposure during CA procedures⁸; in our practice, however, this approach is economically advantageous only in the treatment of complex arrhythmias.⁹

The literature contains no studies on the use of NMSs during HB-CA procedures. The aim of the present study was to evaluate the efficacy, safety, radiation exposure and economic advantages of the systematic use of NMSs during HB-CA in patients with AF refractory

TABLE 1Baseline characteristics ofthe two groups and statistically significant(P-value) differences between Groups Iand II

to medical treatment in comparison with the standard procedure, which uses fluoroscopy alone.

2 | METHODS

2.1 | Study population

This study was a retrospective analysis that involved 124 consecutive patients (pts) with AF refractory to medical treatment who underwent HB-CA procedures from 2012 to 2019. We compared the fluoroscopy data from two groups: 63 pts who underwent HB-CA with fluoroscopy (FL) alone from 2012 to 2015 (Group I) and 61 pts who underwent HB-CA with the additional aid of NMSs (EnSite NavXTM St. Jude Medical, St Paul, MN, USA or CARTO3, Biosense-Webster, Diamond Bar, CA, USA) from 2016 to 2019 (Group II). The baseline patient characteristics of the two groups were also analyzed (Table 1).

Prior to each procedure, we obtained the written informed consent of the patient. The procedures were performed as described in our previous paper.⁸

		Group l (fluoroscopy)	Group II (NMS)	
Patients		61		P-value
Age	Mean [years]	76.8	74.9	P = NS
BMI	Mean [kg/m ²]	25.7	26.4	P = NS
GENDER	F	30	29	P = NS
	М	33	32	
Heart disease	None	4	8	P = NS
	Hypertensive	11	9	
	Valvular	15	7	
	Ischemic	15	16	
	Dilated cardiomyopathy	9	12	
	Other	9	9	
LVEF	<35%	21	16	P = NS
	>55%	18	23	
	35%-44%	10	6	
	45%-55%	14	16	
NYHA	1	6	8	P = NS
	II	18	25	
	III	38	27	
	IV	1	1	
DEVICE	ICD dual chamber	2	1	P = NS
	ICD CRT	20	17	
	ICD single chamber	2	3	
	PMK dual chamber	15	18	
	PMK CRT	5	3	
	PMK single chamber	19	19	

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2.2 | Fluoroscopy and procedure data

In this study, we compared fluoroscopy time and total X-ray exposure. Fluoroscopy time (FT) was defined as the cumulative duration of fluoroscopy during the entire procedure, whereas the patient's radiation dose was assessed as the recorded dose-area product (DAP). Procedure Time (PT) was measured as the interval from the initial recording of intracardiac signals to the final ECG recording before the end of the procedure.

2.3 | Statistical analysis

Nonparametric Mann-Whitney tests (MW-test) were performed to compare all continuous variables and to exam median values between the groups. The χ^2 test was used to compare categorical variables. Statistical analyses were conducted by means of R software, Version 3.4.3¹⁰ (*The R Foundation for Statistical Computing*). A P < .05 was considered significant.

2.4 | Economic analysis

The economic impact of the X-ray dose reduction resulting from the use of NMSs in CA procedures was analyzed by means of two methods: the alpha-value (AV)-based method and the value of a statistical life (VSL)-based method. These two methods have been well described in two of our previous papers.^{9,11} The definitions of the methods and the final formulas are summarized below.

The AV-based method adopts the concept of the alpha-value (AV) parameter. AV represents a monetary reference value of units of exposure avoided and can be expressed as € or \$/man-Sievert (\$/man-Sv). A limitation of the AV-based method is the range of values that the AV can have in different countries. In 2018, the Information System on Occupational Exposure (ISOE) of the European Technical Centre published the latest updated survey, conducted from May to July 2017 in order to collect the different AV values used by regulatory bodies. In most cases, regulatory authorities reported that they did not recommend a monetary value of the AV, whereas only three nuclear regulatory authorities-the British Office for Nuclear Regulation, the Slovak Public Health Authority, and the Czech State Office for Nuclear Safety-reported recommendations on the use of AV.¹² In order to obtain a wider and more complete picture, we decided to consider the updated ISOE survey of 2012, which reported several AV values from regulatory bodies in different countries. This is shown in Table2¹³ column entitled AV value in \$(2014-USD)/mSv). In 2016, the United States Nuclear Regulatory Commission (NRC) drew up the "dollar per person-rem conversion factor" for use in cost-benefit analyses of radiation exposure. Its value was updated to \$5.200 (2014-USD) per person-rem, ie, 520 \$/man-millisievert (\$/man-mSv), as reported in Table 2. In this calculation, 1 rem is equal to 10 mSv and 1\$ is equal to 1 US dollar.¹⁴ The advantage of this method is that it enables fast and easy cost-utility analysis, since the cost reduction related to radiation saved is obtained by

Country ^a	AV value in \$(2014-USD)/mSv	HB-CA cost reduction \$(2014-USD)	HB-CA cost- effectiveness
Canada	108	125	No
Czech Republic (min value)	28	33	No
Czech Republic (max value)	137	159	No
Finland	105	122	No
Korea	84	98	No
Netherlands	619	719	No
Romania	777	903	No
Slovakia	45	52	No
Sweden (min value)	76	88	No
Sweden (max value)	386	449	No
Switzerland	3384	3932	Yes
United Kingdom (min value)	17	20	No
United Kingdom (max value)	171	199	No
United States	210	244	No
United States ^b	520	604	No

TABLE 2AV values, expressed as\$(2014-USD)/mSv, in different countries,
and corresponding Cost Reduction
values, expressed in \$(2014-USD), Cost-
Effectiveness, expressed as Yes or No on
adopting the AV method

^aISOE European Technical Center (2012) Man-Sievert Monetary Value Survey (2012 Update). ISOE Information Sheet No. 55, General Distribution November 2012.

^bOffice of Nuclear Reactor Regulation (2016) Reassessment of NRC's Dollar Per Person-Rem Conversion Factor Policy. Final Report. NUREG-1530, Revision 1, Manuscript Completed: September 2016. simply multiplying the ED reduction (ΔE , measured in [mSv]) by the AV value.

$$Cost - Reduction = \Delta E * AV, \tag{1}$$

where AV values are expressed in [\$/mSv] instead of [\$/man-mSv], as they are related to the exposure of a single patient.

The Value of a Statistical Life (VSL) -based method aims to overcome some limitations of the AV-based method. It is based on the concept of the willingness to pay for a specific level of risk reduction. The VSL does not represent the cost value of a person's life, but the amount that a community would be willing to pay to reduce the risk of one person's death. This risk assessment can be made by using the coefficients reported in the recent (2011) report of the United States Environmental Protection Agency (EPA) EPA 402-R-11-001.¹⁵ This document estimates cancer incidence risk and cancer mortality risk as a result of low doses of ionizing radiation in the US population.

The coefficient used to convert ED into the attributable lifetime risk of cancer mortality was estimated on the basis of the risk models described in EPA 402-R-11-001.¹⁵ The EPA's cancer risk model was also adopted by the NRC in its dollar-per-person-rem conversion factor reassessment.¹⁶

The lifetime risk (LR) of cancer mortality is strongly related to the age and gender of the patients exposed. We therefore assumed that, for HB-CA, LR had an average value of 2.44%/Sv in adult males and females aged 75 years.

The VSL estimates differ across countries and also among agencies within the same country. In 2011, the Organization for Economic Co-operation and Development (OECD) published the VSL values.¹⁶ In OECD countries, the recommended VSL range is \$1.45-4.35 million (2005-USD), with a base value of \$2.9 million (2005-USD), whereas in EU-27 countries, the recommendation is between \$1.75-5.25 million (2005-USD), with a base value of \$3.5 million (2005-USD) (see Table 3, column entitled VSL values in millions \$(2014-USD)).

Even in the same country, values differ; in the United States, for example, the Office of Management and Budget (OMB) concluded that the majority of VSL studies across regulatory agencies suggested a value ranging from \$1 million to \$10 million (2001-USD) per statistical life in 2001,¹⁷ updated to \$1.2 million and \$12.2 million (2010-USD) in 2010.¹⁸

The NRC staff estimates are presented in Table 3.¹⁶

Hence, for a single procedure, and on adopting the VSLbased method, the cost reduction can be estimated by means of Equation (1):

$$Cost - Reduction = LARR * VSL = \Delta E * LR * VSL$$
(2)

LARR is the Lifetime Attributable Risk Reduction, which is the product of the Lifetime Risk (LR) of cancer incidence related to X-ray exposure and the ED Reduction (ΔE).

The extra cost of using an NMS during every HB-CA procedure has been calculated as \ge 2,500{\$3,454 (\$2014-USD)} in our context.

3 | RESULTS

3.1 | Total population

Our study considered a total number of 124 pts (Groups I and II) affected by AF refractory to medical therapy who underwent HB-CA procedures. The baseline characteristics of the two groups are summarized in Table 1. There were no significant differences between the two groups.

OECD ^b	VSL values in millions \$(2014-US) HB-CA cost reduction \$(2014-USD)		HB-CA cost-effectiveness
OECD countries	3.5		99		No
OECD EU-27	4.2		119		No
United States Agencies ^a		VSL value \$(2014-U	s in millions SD)	HB-CA cost reduction \$(2014-USD)	HB-CA cost-effectiveness
Environmental Protection Agency (EPA)		8.7		247	No
Department of Transportation (DOT)		9.3		264	No
Department of Homeland and Security (DHS)		8.6		244	No
Food and Drug Administration (FDA)		8.6		244	No
Occupational Safety and Health Administration (OSHA)		9.0		255	No
Office of Management and Budget (OMB) (min value)		1.3		37	No
Office of Management and Budget (OMB) (max value)		13.2		374	No

TABLE 3VSL values, expressed as millions \$(2014-USD), in different countries and United States Agencies, and corresponding CostReduction values, expressed in \$(2014-USD), Cost-Effectiveness, expressed as Yes or No on adopting the VSL method

^aOffice of Nuclear Reactor Regulation (2016) Reassessment of NRC's Dollar Per Person-Rem Conversion Factor Policy. Final Report. NUREG-1530, Revision 1, Manuscript Completed: September 2016

^bOECD (2011), "Valuing Mortality Risk Reductions in Regulatory Analysis of Environmental, Health and Transport Policies: Policy Implications", OECD, Paris, www.oecd.org/env/policies/vsl

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3.2 | Fluoroscopy and procedure data

The use of an NMS resulted in reduced fluoroscopy time in Group II {median value 1.35 min} in comparison with Group I {median value 4.8 min (MW-test, P < .05)}. Accordingly, total X-ray exposure was higher in Group I (8.76 Gy*cm²) than in Group II (2.95 Gy*cm²) (MW-test, P < .05) (Figure 1). The effective dose reduction (Δ E) was estimated to be 1.16 milli-Sievert. The reduction in X-ray exposure was obtained at the cost of prolonging the PT: median values of 40 min in Group I and 50 min in Group II (MW-test, P < .05) (Figure 1).

No complications were reported in both groups. The HB-CA was similarly effective in both groups, although pacemaker dependency was observed in fewer Group II patients (30 (48%) in Group I vs 19 (31%) in Group II, P = .061). In all patients, no regression of atrioven-tricular block was reported at 12-month visit.

3.3 | Economic results

The reduction in the detriment (cost reduction) is caused by the reduced radiation dose when an NMS is used during the HB-CA procedure.

On applying the **AV method**, the cost-effectiveness of HB-CA procedures is strongly related to the AV values adopted in each country. Table 2 reports the countries considered in this study, their adopted AV values in \$(2014-USD as reference), HB-CA cost-reduction, and whether the use of an NMS is advantageous (Yes) or not (No).

In all the countries considered, with the exception of Switzerland, the dose reduction related to the use of NMSs during HB-CA was not advantageous. The economic threshold reference for HB-CA procedures in our EP Laboratory is \$3,454.

For example, in the Netherlands, applying Equation (1) will result in:

Cost - Reduction = $\Delta E * AV = 1.16 [mSv] * 619 [\$/mSv] = \$718.04 (2014 - USD).$ (3)

On applying the **VSL method**, the cost-effectiveness of the HB-CA procedures is also strongly related to the VSL values adopted



FIGURE 1 The Box and Whisker Plots show the trends in the median values of Fluoroscopy Time (FT), expressed in minutes [min], Dose Area Product (DAP), expressed in [Gy*cm²], and Procedure Time (PT), expressed in minutes [min]

by each country or organization. Table 3 reports the countries and agencies considered in this study, their adopted VSL values in millions \$(2014-USD as reference), HB-CA cost reduction, and whether the use of NMSs is advantageous (Yes) or not (No). The economic threshold adopted for HB-CA procedures in our EP Laboratory is \$3,454 (2014-USD).

For example, with regard to the VLS proposed by the Food and Drug Administration (FDA), applying Equation (4) will result in:

Cost - Reduction = LARR * VLS =
$$\Delta E * LR * VLS =$$

1.16 [mSv] * 2.44 [%/Sv] * 8.6 [million\$] = \$243.40 (2014 - USD)
(4)

4 | DISCUSSION

Today, the use of NMSs during the catheter ablation of complex arrhythmias^{19,20} is standard practice; moreover, their use in the ablation of simple arrhythmias in adults and children is increasingly frequent.

The significant reduction in fluoroscopy exposure was an unexpected effect of this use, and this advantage has been validated in several papers based on randomized^{21,22} and nonrandomized studies in adults^{23,24} and pediatric populations.²⁵ However, the effect of the regular use of an NMS during HB-CA procedures has not been investigated in terms of efficacy, safety, and economic advantages.

In our previous paper, we analyzed these aspects in adults^{8,9} and children²⁵ and our final conclusions were as follows: first, the use of NMS enables fluoroscopy exposure to be considerably reduced; second, the economic advantage depends on the specific situation of the EP Laboratory and is directly related to the amount of the effective dose reduction.

In the present study, we demonstrated that performing HB-CA in patients with AF refractory to medical treatment with the aid of an NMS is safe, feasible, and effective in comparison with the use of fluoroscopy alone; moreover, it seems to be more precise in defining the target ablation area, with less frequent induction of pacemaker dependency.

To determine whether the systematic use of NMSs during HB-CA procedures in our EP Laboratory was economically advantageous or not, we applied two cost-benefit methods (AV and VLS). During the analysis, we encountered the same problem as in our previous studies: the two methods show a very large range of parameters; indeed, the values adopted differ not only from one country to another but also even among the various agencies within the same country. Given these limitations, the main conclusion of our study is that, in HB-CA patients, the effective dose reduction obtained through the use of NMSs is very low and therefore not economically advantageous according to the majority of AV and VSL values. Moreover, owing to the short fluoroscopy time and the limited X-ray exposure required to accomplish these simple procedures with the standard approach, a significant cost-effective-ness was not achievable with NMSs at the current cost of NMS use in our Laboratory.

4.1 | Study limitations

In our opinion, the limitations of this study can be summarized as follows:

- 1. The number of patients in the study was low.
- 2. The study was a retrospective analysis and not a prospective randomized study.
- Adopting the EPA's models for the quantification of cancer mortality risk, we did not consider the additional cost associated with nonfatal cancers. Thus, the monetized benefit is underestimated.
- 4. The costs of NMS use are not standardized among institutions; thus, the results may not be applicable to other centers.
- The reduction in fluoroscopic time with NMSs might prolong the longevity of fluoroscopic machine and positively contribute to economic cost-effectiveness. This aspect was not evaluated with the current model.
- 6. We did not take into account the positive effect of the X-ray reduction on the health of EP Laboratory workers, which is no minor issue.² However, as we did not record worker doses, this analysis was not possible.

5 | CONCLUSIONS

Our retrospective analysis compared the use of an NMS during HB-CA with the traditional system, which uses fluoroscopy alone. We found that the use of an NMS during HB-CA was safe and effective and reduced fluoroscopy time and total X-ray exposure. However, in our practice, this reduction did not prove economically advantageous.

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CONFLICTS OF INTEREST

The authors declare that they have no conflicts of interest.

DISCLOSURE

The present study was performed as part of the employment of the authors at their hospital institutions.

DATA AVAILABILITY STATEMENT

The data used to support the findings of this study are available from the corresponding author upon request.

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