Cost-Effectiveness Analysis Farapulse™ Pulsed Field Ablation (PFA) in Patients with Paroxysmal Atrial Fibrillation

Öztürk F[1] , Kurnaz M[1] , Ekinci A[2] , Woodward E[3] , Uffenorde S[3] , Giabbani I[3] , Maragoni A[3] , Okcun S[1] , Kockaya G[1]

[1]ECONiX Research, Istanbul, Türkiye, [2]Boston Scientific Corporation, Ankara, Türkiye, [3]Boston Scientifi Corporation, Marlborough, MA, USA, Dubai, Dubai, United Arab Emirates

INTRODUCTION

- Atrial Fibrillation (AF) is recognized as the most prevalent sustained cardiac rhythm disorder worldwide, with an increasing global prevalence[1].
- Data from the Framingham Heart Study demonstrates a threefold increase in AF prevalence over the last fifty years. The Global Burden of Disease project estimated that around 46.3 million individuals globally were afflicted with AF in 2016. It is projected that at least 3 to 6 million individuals in the United States and 9 million individuals over 55 years old in Europe are affected by AF[2].
- The FARAPULSE Pulsed Field Ablation (PFA) represents a novel, non-thermal method for cardiac ablation, fundamentally differing from traditional approaches. The FARAPULSE PFA involves the instantaneous creation of a therapeutic electric field within the heart by a purpose-built catheter. Through a process known as irreversible electroporation, the targeted cardiac tissue is electrically inactivated for ablation while preserving collateral tissues.

The aim of this study is to undertake a comprehensive cost-effectiveness analysis for the FARAPULSE™ PFA system, juxtaposing it with thermal ablation medical devices in patients diagnosed with paroxysmal AF. This endeavor seeks to elucidate the economic and clinical utility of the FARAPULSE PFA system, offering vital insights that could inform clinical decisions and healthcare policies pertaining to atrial fibrillation management.

METHOD

- This comprehensive health economic analysis was rigorously conducted from the vantage point of the Social Security Institution (SGK) over a ten-year span. The analysis meticulously accounted for direct costs and years of life gained, with clinical data sourced from relevant studies and integrated into a Markov model.
- Economic data, including costs associated with medication, medical devices, stroke events, and hospitalization, were calculated in strict accordance with SGK standards. The analysis consistently assumed full patient adherence to treatment and the completion of all essential diagnostic tests, covered under the SGK reimbursement framework. The designated time frame for this cost-effectiveness analysis was firmly set at a decade.

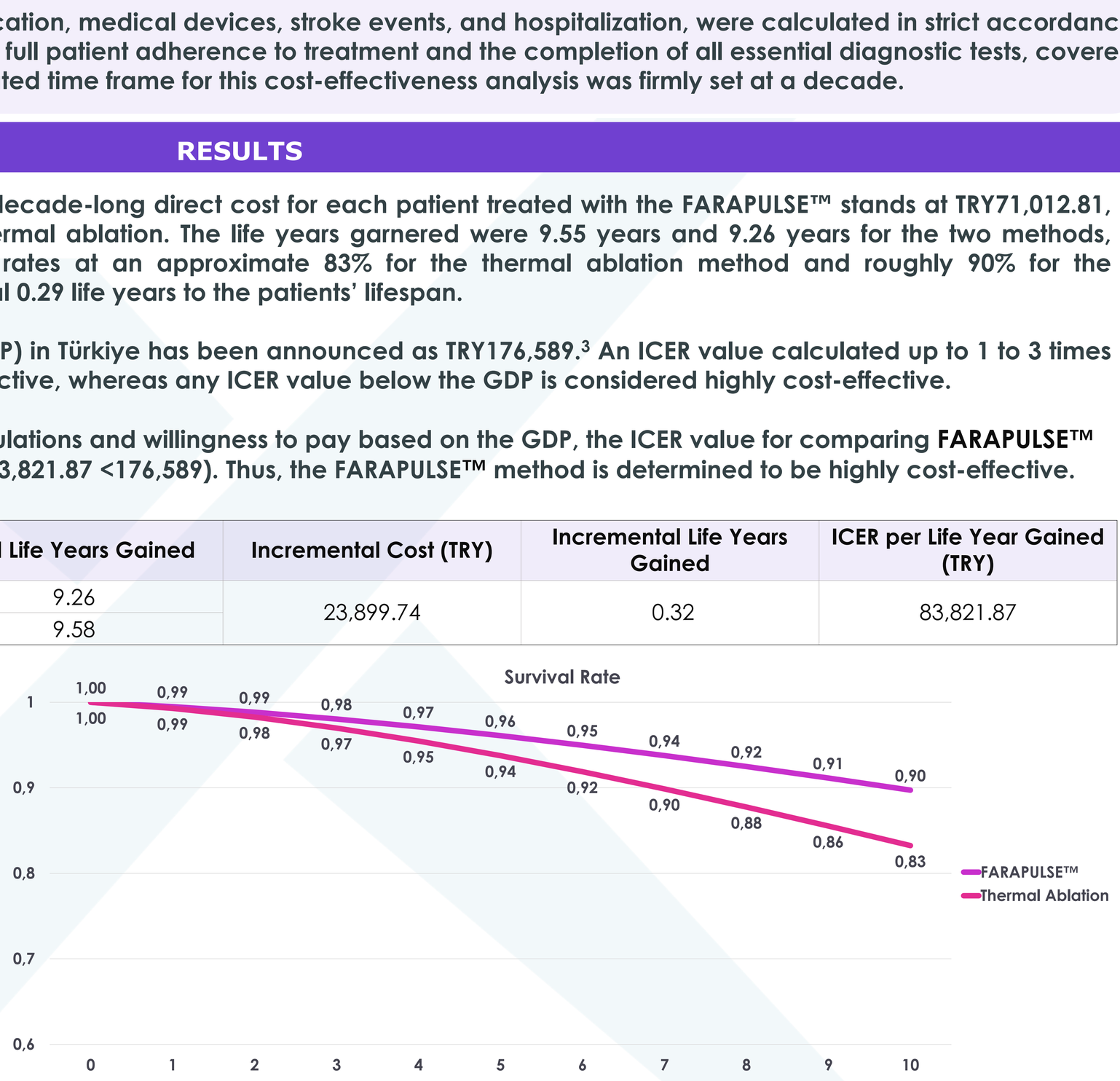
RESULTS

- The conducted analysis revealed that the average decade-long direct cost for each patient treated with the FARAPULSE™ stands at TRY71,012.81, compared to TRY47,113.07 for those undergoing thermal ablation. The life years garnered were 9.55 years and 9.26 years for the two methods, respectively. The calculations showcased survival rates at an approximate 83% for the thermal ablation method and roughly 90% for the FARAPULSE™, with the latter contributing an additional 0.29 life years to the patients' lifespan.
- For 2022, the per capita Gross Domestic Product (GDP) in Türkiye has been announced as TRY176,589.[3] An ICER value calculated up to 1 to 3 times the 2022 GDP (up to TRY529,767) is deemed cost-effective, whereas any ICER value below the GDP is considered highly cost-effective.
- When interpreting cost-effectiveness in terms of calculations and willingness to pay based on the GDP, the ICER value for comparing **FARAPULSE™** and **thermal ablation** treatments is below the GDP (83,821.87 <176,589). Thus, the FARAPULSE™ method is determined to be highly cost-effective.

Treatment	Total Cost (TRY)	Total Life Years Gained	Incremental Cost (TRY)	Incremental Life Years Gained	ICER per Life Year Gained (TRY)
FARAPULSE™	47,113.07	9.26	23,899.74	0.32	83,821.87
Thermal Ablation	71,012.81	9.58			

TRY83,821.87 < **TRY176,589**

Highly Cost-Effective



CONCLUSIONS

- The economic evaluation, incorporating clinical advantage, incremental life years attained, and from the viewpoint of the SGK, unequivocally illustrates the economic and societal advancements conferred by the FARAPULSE™ PFA system.
- This assessment substantiates the inclusion of the aforementioned system within the reimbursement framework for individuals diagnosed with paroxysmal atrial fibrillation in Türkiye, amplifying both health and economic benefits within the societal context.

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Abbrevations:AF:Atrial Fibrillation, PFA: Pulsed Field Ablation, SGK:Social Security Institution, ICER: Incremental Cost-effectiveness Ratio, GDP: Gross Domestic Product, TRY: Turkish Lira

CONTACT

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TUR Ondokuz Mayıs Üniversitesi, Atakum Yerleşkesi, Teknopark, *Atakum, Samsun, Türkiye*

EST Harju maakond, Tallinn, Kesklinna linnaosa, Tornimäe tn 5, *Estonia*

TUN 26 Avenue Mohamed Abdelwaheb, Tunis 2092, *Tunisia*

Phone: +90 850 255 19 34

E-mail: hello@econix.net

Web: http://www.econix.net

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