Cost-Effectiveness Analysis of Left Atrial Appendage Closure with the Watchman Flx device in Patients with Non-Valvular Atrial Fibrillation

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INTRODUCTION

- Atrial Fibrillation (AF) is globally acknowledged as the most widespread continuous cardiac rhythm anomaly, experiencing a notable surge in worldwide prevalence.[1]
- Evidenced by data extracted from the Framingham Heart Study, the past half-century has witnessed a threefold augmentation in the prevalence of AF. The comprehensive Global Burden of Disease project approximated the global affliction of AF in 2016 to encompass around 46.3 million individuals. Forecasts estimate a significant impact on at least 3 to 6 million individuals in the United States and 9 million individuals exceeding 55 years of age in Europe.[2]
- The Watchman FLX Left Atrial Appendage Closure (LAAC) device emerges as a potential alternative to anticoagulant medications for selected patients with non-valvular atrial fibrillation, aiming to preclude the onset of potentially life-threatening stroke.

This study is committed to a meticulous evaluation of both economic and clinical advantages presented by the Watchman FLX LAAC device for patients diagnosed with non-valvular atrial fibrillation, employing the perspective of the Social Security Institution (SGK) in Türkiye.

METHOD

- A comprehensive cost-effectiveness analysis was meticulously conducted to juxtapose the Watchman FLX LAAC method with the conventional non-vitamin K antagonist oral anticoagulant (NOAC) method. This systematic analysis incorporated direct expenses and years of life acquired as paramount outcome metrics.
- Clinical data integrated into the Markov model were derived exclusively from established literary studies, ensuring robustness and reliability in the evaluation. The economic aspects encompassed within this study — which include the expenditures associated with medication, medical apparatus, stroke incidents, hospitalization, and bleeding events — were rigorously computed in alignment with the standards set by the SGK, further reinforcing the analytical precision and relevance of this assessment.
- The time horizon has been set at 10 years for the cost-effectiveness analysis. While conducting economic analyses, it is assumed that all patients are fully compliant with the treatment. Additionally, it is anticipated that all patients have completed the necessary laboratory and imaging tests within the coverage of SGK reimbursement.

RESULTS

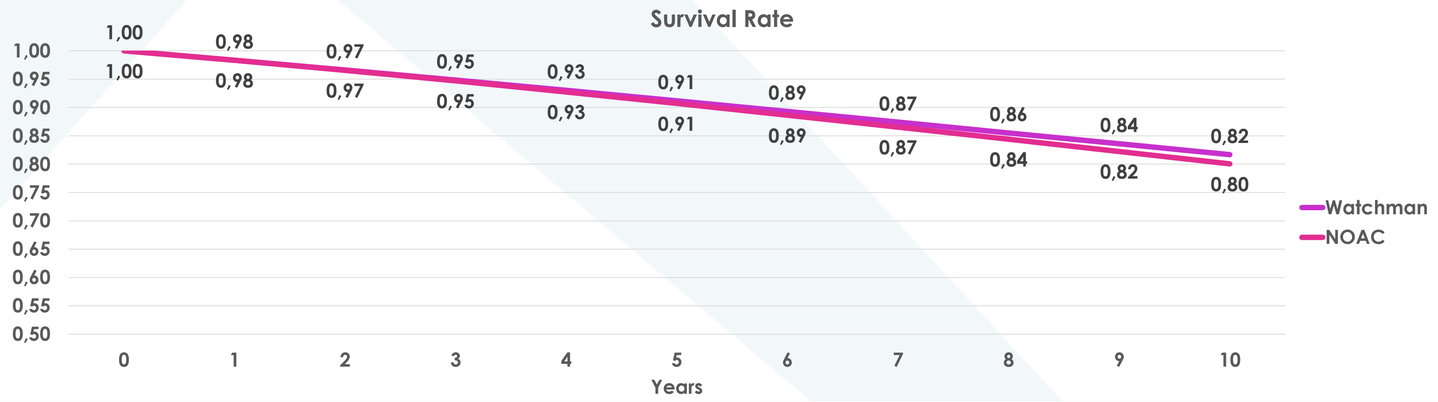
- The economic analysis has been conducted from the perspective of the SGK, a reimbursement institution in Türkiye. The findings of the analysis ascertain that the average 10-year direct cost per patient for the Watchman FLX LAAC method is TRY139,272.23, with life years gained amounting to 9.02 years. It has been observed that the Watchman FLX LAAC presents an incremental cost of TRY93,604.22 and an incremental gained life year of 0.07 years. Based on the calculations conducted, the survival rates have been estimated to be approximately 80% for NOAC treatment and approximately 82% for the application of Watchman FLX LAAC. Conversely, the NOAC method incurs an average 10-year direct cost of TRY45,668.01 per patient, with life years gained totaling 8.95 years. The study's results determined the Incremental Cost-Effectiveness Ratio (ICER) for the Watchman FLX LAAC method in comparison to the NOAC method to be TRY1,418,623.49.

- The Gross Domestic Product (GDP) per capita in Türkiye was announced to be TRY85,672 for the year 2021.[3] For the year 2022, the GDP has been estimated using linear regression analysis and is found to be TRY181,104. It is suggested that the cost-effectiveness threshold for health technologies used in the treatment of rare diseases in Türkiye should be TRY1,811,040, which is ten times the per capita GDP of TRY181,104.
When interpreting cost-effectiveness in terms of calculations and willingness to pay based on the GDP, the ICER value for comparing **Watchman FLX LAAC** and **NOAC** treatments is below the GDP (1,418,623<1,811,040). Thus, the Watchman FLX LAAC method is determined to be cost-effective.

Treatment	Total Cost (TRY)	Total Life Years Gained	Incremental Cost (TRY)	Incremental Life Years Gained	ICER per Life Year Gained (TRY)
NOAC	45,668.01	8.95	93,604.22	0.07	1,418,623.49
Watchman FLX LAAC	139,272.23	9.02			

TRY1,418,623 < **TRY1,811,040**

Cost-Effective



CONCLUSIONS

- The clinical benefits provided by the Watchman FLX LAAC, alongside additional life years and enhanced quality of life, are evident. When considering the perspective of SGK reimbursement, not only the direct costs and saved life years are significant outcome measures.
- The cost-effectiveness data presented within the calculated cost-effectiveness model underscore the public and societal advantages of including the Watchman FLX LAAC in the SGK reimbursement scope for the treatment process of atrial fibrillation patients in Türkiye.

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Abbrevations: LAAC: Left Atrial Appendage Closure SGK:Social Security Institution, NOAC: non-vitamin K antagonist oral anticoagulant, ICER: Incremental Cost-effectiveness Ratio, GDP: Gross Domestic Product, TRY: Turkish Lira

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