Efficacy and Safety of Aspirin in Low-Risk non-Valvular Atrial Fibrillation with 1 Non-Sex Risk Fator : A nationwide population-based study

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저위험 비판막성 심방세동 환자에서 아스피린의 안전성과 효과성에 관한 연구: 건강보험공단 빅데이터 기반 연구

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Abstract

Oral anticoagulants (OACs) are recommended in patients with non-valvular atrial fibrillation (AF). However, the role of aspirin as an alternative to OACs on in intermediate AF patients (CHA_2DS_2 -VASc of 1 [male] or 2 [female]) remains controversial.

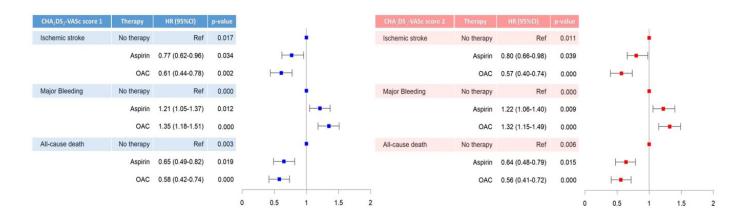
Using National Health Insurance Service database, including 34,701 non-valvular AF patients with 1 non-sex stroke risk factor (CHA₂DS₂-VASc of 1 [male] or 2 [female]), we assessed the risk of clinical outcomes in AF patients according to antithrombotic therapy. Major bleeding was defined as intracranial hemorrhage or gastrointestinal bleeding.

We enrolled 34,701 patients (males with CHA₂DS₂-VASc score of \leq 1 and females with CHA₂DS₂-VASc score of \leq 2) using the Korean National Health Insurance Service database. The annual ischemic stroke rate was lower in aspirin treated male and female patients (1.03%/year, 1.06%/year, respectively) compared to untreated patients (1.32%/year, 1.36%/year, respectively) with hazard ratios of 0.77 (95% confidence interval [CI], 0.62 - 0.96, p = 0.034) for males and 0.80 (95%CI, 0.66 - 0.98, p = 0.039) for females. The OACs treated male and female (0.72%/year, 0.82%/year, respectively) patients had a lower risk of ischemic stroke compared to untreated patients with HR of 0.61 (95% CI, 0.44 - 0.78, p = 0.002) for males and 0.57 (95%CI, 0.40 - 0.74, p < 0.001) for females. Also, the aspirin (male: HR 0.65, 95% CI 0.49-0.82, p = 0.019; female: HR 0.64, 95% CI 0.48-0.79, p = 0.015) and OACs (male: HR 0.58, 95% CI 0.42-0.74, p < 0.001; female: HR 0.56, 95% CI 0.41-0.72, p < 0.001) were associated with a significantly lower risk of all-cause death compared with no therapy. However, the risk of major bleeding was higher in aspirin or OACs treated patients compared with untreated patients.

Aspirin play a beneficial role in the prevention of ischemic stroke and all-cause death in low-risk AF patients with 1 non-sex risk factor and is associated with a higher risk of bleedings events with OACs compared with no-therapy and associated with a similar risk of similar events compared with OACs.

[Table 1] The annual incidence rate of clinical outcomes according to each antithrombotic therapy

	Therapy -	CHA2DS-VASc score of 1 (male)			CHA2DS-VASc score of 2 (female)		
		Total	E vent	IR (95% CI)	Total	E vent	IR (95% CI)
Ischemic stroke	No therapy	3672	85	1.32 (1.18-1.46)	1931	50	1.36 (1.17-1.55)
	Aspirin	11221	235	1.03 (0.96-1.10)	7612	161	1.06 (1.00-1.12)
	OAC	6419	94	0.72 (0.65-0.80)	3846	65	0.82 (0.72-0.92)
Major Bleeding (ICH+GI Bleeding)	No therapy	3672	65	1.74 (1.52-1.96)	1931	36	1.82 (1.52-2.12)
	Aspirin	11221	216	2.11 (1.97-2.25)	7612	149	2.17 (1.99-2.35)
	OAC	6419	133	2.24 (2.05-2.43)	3846	81	2.29 (2.04-2.54)
All-cause death	No therapy	3672	115	1.91 (1.73-2.09)	1931	69	1.97 (1.73-2.21)
	Aspirin	11221	314	1.39 (1.31-1.47)	7612	220	1.51 (1.41-1.61)
	OAC	6419	146	1.29 (1.18-1.40)	3846	80	1.36 (1.21-1.51)



[Figure 1] Hazard ratio of clinical outcomes according to according to each antithrombotic therapy