

Commentary: Not Aricept but Donepezil Should not Permit for Lewy Body Disease without Proper Clinical Trials

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Abstract

In Japan, only Aricept (original medicine of donepezil) is permitted for treatment of Lewy Body Disease (LBD). Other generic medicines of donepezil are not allowed for treatment of LBD because of patent for treatment of LBD. Since Nov in 2018, other generic medicines will be allowed for treatment of LBD because of ending of patent of Aricept for treatment for LBD. However, we speculate that when compared with Alzheimer's Disease (AD), in LBD effective range of donepezil might be narrowed than in AD. Therefore, when the mean effective dose is almost same, there are three types of patients in LBD. First, standard dose of prescription of donepezil are within the optimal dose, however, same dose of donepezil is not effective in second type of LBD patients, and that induce side effect in third type of LBD patients.

Keywords: Alzheimer's Disease (AD); Aricept (original medicine of Donepezil); Effective range; Lewy Body Disease (LBD)

Abbreviations: AA: Anticholinergic Activity; Ach: Acetylcholine; AD: Alzheimer's Disease; SAA: Serum Anticholinergic Activity; S: Schizophrenia

Commentary

In Japan, only Aricept (original medicine of Donepezil) is permitted for treatment of Lewy Body Disease (LBD) [1]. Other generic medicines of donepezil are not allowed for treatment of LBD because of patent for treatment of LBD. Since Nov in 2018, other generic medicines will be allowed for treatment of LBD because of ending of patent of Aricept for treatment for LBD.

However, we consider that not Aricept but generic medicines of donepezil should not permit for Lewy body disease without proper clinical trials mainly for two reasons. One is that the interactions between main component, i.e., donepezil, and other components in order to aggregate and to use as a pill form. The main component is same

between original medicine, i.e., Aricept, and other generic medicines. However, other components are different from those of original medicine. Therefore, ingestion, absorption, distribution, transfer to the central nervous system and the degree of action to central nervous system and peripheral tissues are different for each medicines.

The other reasons are that LBD is sensitive against psychotropic medicines such as antipsychotics, however, even Aricept induces side effects such as sedations. We speculate that when compared with Alzheimer's Disease (AD), in LBD effective range of donepezil might be narrowed. Therefore, when the mean effective dose is almost same for example, $A1=A2$, $B1=B2$, $C1=C2$, in (Figure 1), among B1, A1, A2 in AD and A2 in LBD, standard dose of prescription of donepezil are within the optimal dose, however, in case A1 in LBD standard dose of prescription of donepezil is not effective and in Case C1 in LBD that induce side effect (Figure 1).

From these two reasons, generic medicines of donepezil should not be permitted for LBD without proper clinical trials.

Conflict of Interest

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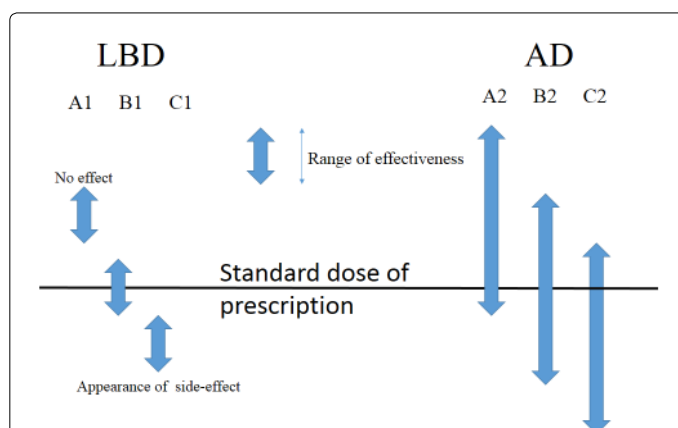


Figure 1: We speculate that when compared with Alzheimer's Disease (AD), in Lewy Body Disease (LBD) effective range of donepezil might be narrowed than in AD. Therefore, when the mean effective dose is almost same (for example, $A1=A2$, $B1=B2$, $C1=C2$), among B1, A1, A2 in AD and A2 in LBD, standard dose of prescription of donepezil are within the optimal dose, however, in case A1 in LBD standard dose of prescription of donepezil is not effective and in Case C1 in LBD that induce side effect.

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Author Contributions

Koji Hori mainly coordinates the study regarding to AA or SAA. Michiho Sodenaga, approve the concepts of this article, gave advise and checked the article.

Reference

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