Examination about clinical efficacy and safety of active use of tolvaptan for decompensated congestive heart failure cases

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Background: In Japan, Tolvaptan is approved for use as a potent oral diuretic, mainly for severe congestive heart failure. However, over time since the launch of Tolvaptan, there have been many reports of its usefulness when used earlier in milder cases. Based on this background, in August 2015, our facility introduced a clinical pathway (PATH) for acute care for cases with decompensated congestive heart failure (DCHF), in which immediate use of tolvaptan with conventional diuretics were stipulated to keep patient’s activity by early diuresis.

Purpose: In this study, we verified the clinical usefulness and safety of PATH for DCHF that prescribes the active use of tolvaptan.

Methods: From April 2014 to July 2022, 846 DCHF cases admitted to our hospital for the first time were included. They were divided into two groups, N-group(154 cases before introduction of PATH) and P-group(692 cases introduced PATH and prescribed Tolvaptan as stipulated). We investigated their implementation status of each medical treatment in acute phase and hospitalization period(HP), and compared the difference between the two groups. And in P-group, we investigated the occurrence of adverse event(AE), deterioration of renal function (R-event) and hypernatremia (N-event) that required unplanned discontinuation of tolvaptan use, and we investigated the clinical features about the cases with each adverse event.

Results: There was almost no difference in the patient background before admission or the patient's condition at admission. In P-group, the performance rate of each acute medical care for DCHF was lower and their performance period was shorter compared in N-group. The performance rate of cardiac rehabilitation was higher and its starting time was earlier in P-group. (Figure 1) As a result, HP was significantly shorter in P-group. AE incidence in P-group were 2.2%(R-event) and 4.8%(N-event). Mean age tended to be higher and cognitive function was lower in both AE cases. Cases with R-event were more likely to have pre-existing renal insufficiency. In N-event cases, their activity level before admission was lower and blood sodium level at admission was higher. Most of the N-event(85%) occurred within 7 days.(Figure 2)

Conclusions: With the introduction of unique clinical pathway that stipulates the active use of tolvaptan, the acute care of cases with decompensated congestive heart failure had been greatly simplified and streamlined, and the hospitalization period had been shortened. Although it is unlikely that all the results were due to the medicinal effects of Tolvaptan, it was thought that the realization of early mobilization due to its strong diuretic effect was linked to these results. A certain rate of feared adverse events, especially hypernatremia, was found to occur, but the rate appeared to be acceptable. However, in elderly and cognitively impaired cases, special caution seemed to be required for several days after the start of tolvaptan use.
Figure 2