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Title: Usefulness of selective neutrophil elastase inhibitor, sivelestat, in ALI patients with SIRS

Dr. Seigo 10431 Miyoshi seigom@m.ehime-u.ac.jp MD [1], Dr. Ryoji 10432 Ito ryito@m.ehime-u.ac.jp MD [1], Dr. Hitoshi 10433 Katayama hkatayam@m.ehime-u.ac.jp MD [1], Dr. Kazunori 10434 Irifune kirifune@m.ehime-u.ac.jp MD [1], Prof. Hironobu 10435 Hamada hirohamada@hiroshima-u.ac.jp MD [2], Dr. Toshimitsu 10436 Suwaki toshimitsu_suwaki@ni.sbh.gr.jp MD [3], Dr. Norihiko 10437 Nakanishi c-nakanishi@eph.pref.ehime.jp MD [4], Dr. Takanori 10439 Kanematsu tkanematsu@matsuyama.jrc.or.jp MD [5], Dr. Kentaro 10440 Dote dotek@m.ehime-u.ac.jp MD [6], Prof. Mayuki 10441 Aibiki aibiki@m.ehime-u.ac.jp MD [7] and Prof. Jitsuo 10442 Higaki jhigaki@m.ehime-u.ac.jp MD [1]. [1] Department of Integrated Medicine and Informatics, Ehime University Graduate School of Medicine, Toon, Ehime, Japan ; [2] Department of Health and Sports Medical Sciences, Graduate School of Health Sciences, Hiroshima University, Hiroshima, Japan ; [3] Department of Respiratory Medicine, Sumitomo Besshi Hospital, Niihama, Ehime, Japan ; [4] Department of Respiratory Medicine, Ehime Prefectural Central Hospital, Matsuyama, Ehime, Japan ; [5] Department of Respiratory Medicine, Matsuyama Red Cross Hospital, Matsuyama, Ehime, Japan ; [6] Intensive Care Division, Ehime University Hospital, Toon, Ehime, Japan and [7] Department of Emergency Medicine, Ehime University Hospital, Toon, Ehime, Japan .

Body: Background: Neutrophil elastase is known to be an important mediator of acute lung injury (ALI) in systemic inflammatory response syndrome (SIRS). Sivelestat is a neutrophil elastase inhibitor, but the clinical efficacy of sivelestat in patients with ALI associated with SIRS is now controversial. Methods: A retrospective data analysis of 110 ALI patients with SIRS was conducted to investigate the effects of sivelestat. The clinical efficacy of sivelestat was evaluated based on the survival rate and ventilator free days (VFD) and changes between before and 7 days after administration of sivelestat in PaO_2/F_IO_2 (P/F) ratio, white blood cell count, levels of C-reactive protein and procalcitonin (PCT). Results: Sivelestat group included 70 patients, and control group included 40 patients without administration of sivelestat. VFD was significantly higher, and P/F ratio significantly improved in the sivelestat group compared to the control group. Univariate analysis showed that administration of sivelestat is not an independent predictor of survival of ALI patients with SIRS. In non-septic patients, there was no significant efficacy of administration of sivelestat on the survival rate, VFD and changes in P/F ratio. In septic patients, the survival rate was significantly higher in the sivelestat group than in the control group (p=0.008). Administration of sivelestat significantly increased VFD and P/F ratio, and reduced the levels of PCT in septic patients. Conclusion: Our results suggest that sivelestat might have beneficial effect on the respiratory condition of the ALI patients with SIRS. Furthermore, sivelestat administration tends to associate with survival in patients with ALI with sepsis.