INTRODUCTION

Delirium is a particularly common morbidity after surgery. Postoperative delirium makes patient management much more difficult, increases costs, and causes severe discomfort to the patient\(^1\). Delirium is also associated with increased postoperative mortality and morbidity and with delayed functional recovery\(^2,3\).

PROTOCOL DIGEST OF THE STUDY

Purpose

The aim of this study was to identify predictors for postoperative delirium.

Summary of TJ-54 study

A prospective, multi-institutional, randomized, phase II trial was performed in patients receiving surgery for gastrointestinal or lung malignancy in Japan\(^4\). The eligible patients were centrally randomized to receive either TJ-54 or control during their per operative care (UMIN ID000005423). Inclusion criteria: (1) Patients ≥ 70 years of age who underwent surgery for gastrointestinal or lung malignancies were considered eligible for this study. (2) All participants were required to have an Eastern Cooperative Oncology Group performance status ≤ 2; (3) to receive MMSE before enrollment and to have an adequate hepatic, renal, and bone marrow function. Medical conditions that rendered a patient unsuitable for inclusion in the study according to the opinion of the investigator were also considered to be exclusion criteria for this study. Assuming an incidence of delirium of 5% in the TJ-54 group and 20% in the control group, a sample size of 88 for each group was estimated to have at least 80% power under a two-sided significance level of 10%. Therefore, a target sample size of 200 patients was required. The primary endpoint was the incidence of delirium after surgery and safety.

Assessment of postoperative delirium

The American Psychiatric Association’s the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) was used to assess the patients who were suspected of postoperative delirium. DSM-IV lists key features that characterize delirium as follows: Disturbance of consciousness and a change in cognition or the development of a perceptual disturbance that develops over a short period of time and tends to fluctuate during the course of the day.

Evaluations and statistical analyses

A uni- and multivariate logistic regression analyses was performed to identify risk factors for morbidity. Comparisons between the two groups were analyzed by chi-square test. All statistical tests were two-sided, and significance was set at P < 0.05. The SPSS software package (v11.0 J Win, SPSS, Chicago, IL) was used for all statistical analyses.

Data analysis

This study is an ancillary study of the TJ-54 study. Individual Patients’ clinic pathological data of a total of 167 patients from the trial was already collected and their
analyses have been completed. Age, gender, and type of surgery were evaluated for the candidate markers for emergence of delirium in the present study. Detailed results of overview of this integrated data will be published elsewhere after scrutinized examination and model based analysis of all the retrieved results.

Acknowledgement
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Conflict of interest statement
None declared.

References