Effect and cost of treatment for acute pancreatitis with or without gabexate mesylate: a propensity score analysis using a nationwide administrative database

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

CRD summary
This study evaluated the cost and effectiveness of gabexate mesylate for adult patients with acute pancreatitis. The authors concluded that treatment with gabexate mesylate was not justified because of higher costs and no significant effects. There was potential for bias in the evidence, but the analyses were appropriate and the authors' conclusions are reasonable.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
This study evaluated the cost and effectiveness of gabexate mesylate, for adult patients with acute pancreatitis.

Interventions
Gabexate mesylate, as the only protease inhibitor, was compared with no protease inhibitor.

Location/setting
Japan/in-patient.

Methods
Analytical approach:
The cost-effectiveness analysis was based on observational data from a Japanese national database. Only those patients who were treated with gabexate mesylate alone or no protease inhibitor were eligible for analysis. The time period of the analysis appears to have been the duration of in-patient stay. No study perspective was stated.

Effectiveness data:
The key clinical outcome was mortality in hospital. This was a retrospective observational study, and one-to-one propensity matching was used to try to account for confounding factors, which included age, gender, a measure of comorbidity, and prognostic factors for acute pancreatitis. In total, 707 patients who met the inclusion criteria for the intervention group were matched to 707 patients who met the criteria for the control group. The average in-hospital mortality was compared between the groups, and a multivariate logistic regression analysis, for in-hospital mortality, was performed to estimate the treatment effect of gabexate mesylate, with adjustment for the severity of acute pancreatitis and the propensity score.

Monetary benefit and utility valuations:
Not relevant.

Measure of benefit:
The measure of benefit was in-hospital mortality.

Cost data:
The resource items included in the analysis were the drugs, in-patient stay, and surgical, pharmaceutical, laboratory and other in-patient services. The prices for these items were their reference prices from the Japanese national fee schedule. The costs were reported in US $.
Analysis of uncertainty:
The probability of incorrectly detecting a treatment effect, where there was none, was calculated for both the difference in mortality and in costs. Confidence intervals were estimated for the odds ratio for death, derived from the logistic regression analysis.

Results
The odds ratio for in-hospital death, for patients in the gabexate mesylate group was 1.15 (95% CI 0.59 to 2.23).

The population was divided into those with non-severe and those with severe acute pancreatitis. The median costs for non-severe patients were $4,928 (IQR 3,701 to 7,541) for the gabexate mesylate group and $4,374 (IQR 3,169 to 6,670) for the control group. This difference was statistically significant (p< 0.001). The median costs for severe patients were $6,605 (IQR 4,685 to 11,710) for the gabexate mesylate group and $6,490 (IQR 4,441 to 13,345) for the control group. This difference was not statistically different (p= 0.764).

Authors' conclusions
The authors concluded that treatment for acute pancreatitis, using gabexate mesylate, was not justified because of higher costs and no significant effects.

CRD commentary
Interventions:
The intervention and control were adequately described, and their selection was relevant for the Japanese setting.

Effectiveness/benefits:
The estimate for the treatment effect was based on retrospective observational data. It is difficult to account for all potential confounding factors in such an analysis, and the authors highlighted this limitation. The propensity matching approach was appropriate for the data available, but it only addressed the known confounders. Mortality appears to have been an appropriate measure of benefit, but quality of life (morbidity) was also important and relevant to patients with acute pancreatitis.

Costs:
Few details of the cost items, included in the analysis, were reported, so it is difficult to check whether the relevant resource use was recorded in the database and subsequently included in the analysis. The authors suggested that it was comprehensive, but did not support this by presenting the details. The resource use estimates and the prices used for those resources, all appear to be directly applicable to the Japanese setting. The unit costs for the resources were not reported, neither was the price year for the analysis.

Analysis and results:
The statistical analyses appear to have been appropriate for estimating the differences in the treatment effects and costs, as well as providing estimates of the statistical uncertainty. The results were adequately reported. This analysis was based on one clinical study, and the authors appropriately referred to existing clinical trial evidence for the effectiveness of gabexate mesylate. The authors identified relevant limitations to their analysis, such as the retrospective nature of the evidence, and the all-encompassing definition of the intervention (continuous intravenous or regional arterial administration, in various patients).

Concluding remarks:
There was the possibility of bias in the clinical and cost estimates, given the nature of the evidence, but the analyses were appropriate and the authors' conclusions are reasonable.

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