Success and shortcomings of a clinical care pathway in the management of acute nonvariceal upper gastrointestinal bleeding


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.

Health technology
The use of a clinical pathway for patients with acute upper gastrointestinal (GI) bleeding was examined. The clinical pathway was developed by a team including gastroenterologists, a nurse care manager, and a physician member from the emergency department. The key areas of the new guidelines were:

- reduction in the use of intravenous (IV) acid suppression using H2-receptor antagonists (H2-RA);
- reduction in the use of radiological tests; and
- reduction in patient length of stay (LOS) and time from admission to endoscopy.

Guidelines for the initial physical assessment, treatment, admission and discharge criteria, and prompt GI service consultation, were developed.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with acute, nonvariceal upper GI bleeding. The exclusion criteria were:

- chronic GI bleeding;
- patients admitted for end-of-life care, or patients with other life-threatening disease processes in whom the magnitude of the GI bleeding was considered relatively insignificant;
- patients admitted explicitly for surgical intervention;
- patients who were found to be bleeding from varices or from cancer; and
- the refusal of a GI consultation or endoscopy.

Setting
The setting was a hospital. The economic study was carried out in the USA.

Dates to which data relate
The effectiveness and resource use data were gathered from June to December 1997 in the control group, and from
January 1998 to June 1999 in the intervention group. The price year was not reported.

**Source of effectiveness data**
The effectiveness evidence was derived from a single study.

**Link between effectiveness and cost data**
The costing was carried out prospectively on the same sample of patients as that used in the effectiveness study.

**Study sample**
Power calculations were not reported. Data in the comparison group (pre-guideline period) were prospectively gathered for a 6-month period before the implementation of the clinical pathway. Data in the intervention group (post-guideline period) were then prospectively gathered for an 18-month period. A total of 421 patients was included in the analysis, of which 98 (46.9% male) were in the control group and 323 (51.7% male) were in the intervention group. The mean age of the patients was 66 years in the control group and 66.2 years in the intervention group. Six patients were excluded from the intervention group upon applying the exclusion criteria.

**Study design**
This was a prospective cohort study in which the two groups of patients were evaluated prospectively, but not simultaneously. The study was carried out at an academic institution, the University Hospitals of Cleveland, in Ohio, USA. The patients were followed until hospital discharge. No patient was lost to the follow-up assessment.

**Analysis of effectiveness**
All of the patients included in the initial study sample were accounted in the effectiveness analysis. The outcomes used were:

- the number of patients receiving IV H2-RA;
- the mean LOS;
- the number of patients who had plain radiographs of the chest and abdomen; and
- the time from admission to endoscopy.

Patients were also stratified according to the severity of illness, using the "All Patient Refined Diagnosis Related Group" (APR-DRG) classification. This was based on a 4-point scale of severity of illness (0: mild, 1: moderate, 2: severe, 3: catastrophic). The study groups were comparable at baseline in terms of age, gender, and severity of disease. However, there was a non significant trend showing that the patients in the intervention group were more severely ill.

**Effectiveness results**
The number of patients receiving IV H2-RA was 64 (65.3%) in the control group and 154 (47.7%) in the intervention group, (p=0.002).

The mean LOS was 4.58 days (control group) versus 3.78 days (intervention group), (p=0.436).

The mean time from admission to endoscopy was 1.24 days (control group) versus 1.21 days (intervention group), (p=0.770).

No statistically significant differences were observed in the number of patients who had plain radiographs of the chest and abdomen.
Clinical conclusions
The effectiveness analysis showed that the implementation of a clinical pathway led to a reduction in the use of IV H2-RA, but did not affect other outcome measures such as the LOS and use of diagnostic procedures.

Measure of benefits used in the economic analysis
The health outcomes were left disaggregated and no summary benefit measure was used in the economic analysis. In effect, a cost-consequences analysis was carried out.

Direct costs
Discounting was not relevant since the costs were incurred during a short timeframe. The unit costs were not presented separately from the quantities of resources used, and a detailed breakdown of the cost items was not provided. The economic evaluation considered only hospital costs, which were broken down into nine main categories. More specifically, variable labour, variable supplies, variable "other", variable indirect, fixed direct labour, fixed direct equipment, fixed direct facilities, fixed direct "other", and fixed indirect. The cost/resource boundary of the hospital appears to have been adopted. Resource use was derived from the sample of patients included in the effectiveness study and was gathered from 1997 to 1999. The cost data were likely to have been obtained from the hospital finance department. The price year was not reported.

Statistical analysis of costs
The Wilcoxon rank sum test was used to test the statistical significance of differences in the costs. Trends in the economic data during the period of guideline implementation were examined using the Kruskal-Wallis test.

Indirect Costs
The indirect costs were not considered.

Currency
US dollars ($).

Sensitivity analysis
Sensitivity analyses were not performed.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The total costs per patient were $5,381 in the control group and $4,627 in the intervention group, (p=0.084).

The variable direct costs per patient were $2,269 in the control group and $1,952 in the intervention group, (p=0.163).

Similar results were obtained when the patients were stratified by severity of illness, although there was a non significant trend toward a cost-reduction for patients with the least severe illness.

Synthesis of costs and benefits
The costs and benefits were not synthesised because a cost-consequences analysis was carried out.
Authors’ conclusions
The implementation of a clinical pathway for patients with acute gastrointestinal (GI) bleeding reduced the use of intravenous (IV) H2-receptor antagonists (H2-RA), but did not affect other clinical and economic outcomes. It was also noted that it was difficult to control and influence physicians and their decision-making process, especially for those who had not been directly involved in the design of the care pathway.

CRD COMMENTARY - Selection of comparators
The selection of the comparators was appropriate as the new clinical pathway was compared with the pre-guideline period. A detailed description of the guidelines was provided. You should decide whether they are valid comparators in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness evidence came from a prospective cohort study, which was appropriate for the study question because the use of a clinical trial was not feasible. The two groups were evaluated prospectively, but not simultaneously, as the evidence were gathered in two different timeframes. This could have introduced some time-related bias (i.e. factors other than the study intervention could have affected the results of the analysis). This issue was not explicitly addressed in the study. The two study groups were comparable at baseline, but the authors noted that there was a trend towards differences in disease severity. The main drawback of the analysis was the fact that there was no evidence of whether the sample size was appropriate. This could explain the lack of statistical significance in most of the outcome measures used in the analysis. The impact of the intervention on patient health was not clearly investigated, as most of the outcome measures reflected resource consumption rather than changes in patient health.

Validity of estimate of measure of benefit
No summary benefit measure was used in the analysis because a cost-consequences analysis was conducted. Please refer to the comments in the ‘Validity of estimate of measure of effectiveness’ field (above).

Validity of estimate of costs
The perspective adopted in the study was not explicitly stated and only hospital costs were included in the analysis. A breakdown of the cost items was not provided, and the costs were grouped in nine macro-categories. The price year was not reported, which reduces the possibility of reflating the study results in other settings. The source of the data was not explicitly reported. The cost estimates were specific to the study setting and could not be transferred to other contexts. Sensitivity analyses were not performed. Statistical tests were carried out to examine the statistical significance of differences in the costs.

Other issues
The authors made narrative comparisons of their findings with those from other studies. The issue of the generalisability of the study results to other settings was not addressed and sensitivity analyses were not performed. This reduces the external validity of the analysis. The authors attempted to explain the reasons for the failure to impact on the use of radiology procedures. The study referred to patients with acute GI bleeding and this was reflected in the authors’ conclusions.

Implications of the study
The study results showed that there were significant limitations and barriers to the implementation of the clinical pathway for patients with acute GI bleeding. The authors stated that improvements in future design and trials of clinical care pathways to treat acute GI bleeding should have better control over patients’ hospital care and over decisions made about the level of care and discharge. The establishment of dedicated gastroenterology bleeding teams and units could represent an optimal setting for the implementation of clinical pathways for acute GI bleeding.
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None stated.

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