Impact of trauma stress ulcer prophylaxis guidelines on drug cost and frequency of major gastrointestinal bleeding

Devlin J W, Claire K S, Dulchavsky S A, Tyburski J G

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 stress ulcer prophylaxis guidelines for trauma patients, aimed at appropriately identifying the patients that would benefit the most from ulcer prophylaxis. The guidelines reported the indications for therapy (cimetidine, sucralfate, or regularly scheduled anti-acid therapy), discontinuation of therapy and choice of agent.

Type of intervention
Guidelines.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients admitted to the emergency department and presenting with multiple traumas. The patients were stratified as minor or moderate-to-severe trauma, according to the Injury Severity Score (ISS). An ISS of less than 9 indicated minor trauma, while an ISS of at least 9 indicated moderate-to-severe trauma. Patients discharged from the hospital less than 24 hours after admission, or transferred directly to a surgical specialty service, were excluded.

Setting
The setting was the emergency department of a tertiary care teaching hospital. The economic study was carried in Detroit (MI), USA.

Dates to which data relate
The effectiveness evidence and resource use data were gathered from November 15, 1997 to January 23, 1998 in the pre-guideline period, and from February 22, to April 19, 1998 in the post-guideline period. The price year was 1997.

Source of effectiveness data
The effectiveness evidence came from a single study.

Link between effectiveness and cost data
The costing was performed retrospectively on the same sample of patients as that used in the effectiveness study.

Study sample
Power calculations were performed. These indicated that a sample of 150 patients in each group had a 0.80 power at a two-sided alpha level of 0.05 to detect a 4% change between the groups in the frequency of major GI bleeding. Two
samples of 150 consecutive eligible patients each were enrolled into the study in the pre- and post-guideline periods. In the pre-guideline sample, the median age was 37.3 (+/- 17) years and 67% were men. In the post-guideline period, the median age was 40.2 (+/- 16.2) years and 73% were men.

Study design
This was a retrospective comparative study where the study groups were not evaluated concurrently but in two distinct timeframes. It was carried out in a single centre (the tertiary care teaching hospital). The patients were allocated to the study groups according to when they were enrolled in the study. The patients were not followed after hospital discharge.

Analysis of effectiveness
All of the patients included in the initial study sample were accounted for in the effectiveness analysis. The primary health outcome used in the analysis was the frequency of major GI bleeding (i.e. number of patients). This was defined as a difference of at least 2 g/dL between two consecutive haemoglobin values in conjunction with clinically apparent coffee-ground emesis, haematemesis, melena, or haematochezia. The number of patients prescribed stress ulcer prophylaxis and meeting (or not meeting) guideline criteria in the post-guideline period was also evaluated. The study groups were comparable at baseline in terms of their demographic and clinical characteristics.

Effectiveness results
The frequency of major GI bleeding was 0.7% (only 1 patient) in the pre-guideline group and 0% (no patients) in the post-guideline group. The difference was not statistically significant.

The total number of patients prescribed stress ulcer prophylaxis was 105 (70%) in the pre-guideline period and 39 (26%) in the post-guideline period, (p<0.0001).

Of the 39 patients who were prescribed stress ulcer prophylaxis in the post-guideline group, only 24 met the guideline criteria. For the 15 that did not meet the guideline criteria, the pharmacist made a recommendation to the surgery house staff to discontinue therapy in 13. However, only 9 patients actually discontinued the therapy.

During the course of the study, pharmacist recommendations also resulted in therapy being discontinued in 14 of the 17 patients who were identified as no longer requiring therapy.

Clinical conclusions
The effectiveness evidence showed that the guidelines were useful in identifying the patients who benefited from stress ulcer prophylaxis, without increasing the frequency of major GI bleeding.

Measure of benefits used in the economic analysis
No summary benefit measure was used in the economic evaluation. A cost-consequences analysis was therefore carried out.

Direct costs
Discounting was not relevant because the costs were incurred in a short time period. The unit costs were not analysed separately from the quantities of resources used. The health services in the economic evaluation were the drugs used for the trauma stress ulcer prophylaxis and administration-related resources, such as syringes and minibags. Pharmacy preparation and dispensing costs were not included in the analysis. The cost/resource boundary adopted in the study was not explicitly stated. The unit costs were estimated on the basis of the average wholesale prices for drugs and other devices. Resource consumption was derived using individualised data coming from the sample of patients involved in the effectiveness study from November 15, 1997 to January 23, 1998 (pre-guideline group) or from February 22 to April 19, 1998 (post-guideline group). The calculation was based on the number of patients prescribed
stress ulcer prophylaxis. The price year was 1997.

**Statistical analysis of costs**
The length of stay and drug costs of the groups were compared statistically using the Mann-Whitney rank sum test.

**Indirect Costs**
The indirect costs were not included in the economic analysis.

**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 were $5,679 in the pre-guideline period and $1,221 in the post-guideline period, (p=0.064).

The median costs did not vary substantially, $28.65 (range: 5.51 - 208.80) versus $34.74 (range: 5.76 - 98.94).

**Synthesis of costs and benefits**
The costs and benefits were not combined due to the cost-consequences design.

**Authors' conclusions**
The implementation of trauma stress ulcer prophylaxis guidelines led to a reduction in the costs of the drugs, without increasing the frequency of major gastrointestinal (GI) bleeding.

**CRD COMMENTARY - Selection of comparators**
The rationale for the choice of the comparator was clear. The authors compared the new guidelines with the usual practice before the guidelines were implemented. You should decide whether it represents a valid comparator in your own setting.

**Validity of estimate of measure of effectiveness**
The effectiveness analysis used a retrospective comparative study, which was appropriate for the study question. However, such an observational study entails some problems, such as bias and confounding, as the authors noted. They further commented that a well-controlled randomised controlled trial would have eliminated many of these problems. In addition, it was highlighted that due to staggered rotations, some staff members may have remained unfamiliar with the new guidelines. Finally, time-related factors other than the study intervention may have affected the results of the analysis. However, some strengths of the analysis have to be noted. First, the two study groups were well balanced at baseline. Second, all of the patients were evaluated in the effectiveness study. Third, power calculations were performed. Overall, the study sample appears to have been representative of the study population, although the authors stated that some trauma sub-population at increased risk of stress gastritis was under-represented.
Validity of estimate of measure of benefit
No summary benefit measure was used in the economic analysis. The analysis was therefore categorised as a cost-consequences study.

Validity of estimate of costs
The perspective adopted in the study was not stated. Only the costs strictly related to the use of prophylactic drugs were included in the analysis. The authors stated that the aim of the study was not to undertake an economic evaluation of the new guidelines, but to estimate the impact of the new intervention. The unit costs were not analysed separately from the quantities of resources used. Sensitivity analyses were not performed and the cost estimates were specific to the study setting. Statistical analyses were conducted, but only to test the statistical significance of the total estimated costs. The price year was reported, thus making reflation exercises in other settings easy.

Other issues
The authors made several comparisons of their findings with those from other studies. The results of the present study were more favourable than those observed in other patient series (such as the low frequency of stress-related bleeding). The authors did not address the issue of the generalisability of the study results in other settings and sensitivity analyses were not performed. Thus, the external validity of the analysis was low. The study referred to trauma patients and this was reflected in the conclusions of the analysis.

Implications of the study
The study results suggest that the introduction of new guidelines for trauma stress ulcer prophylaxis led to cost advantages, without affecting the frequency of stress-related GI bleeding. The authors highlighted that the study left many questions unanswered and that future research should be based on a randomised, well-controlled, prospective trial.

Source of funding
None stated.

Bibliographic details

PubMedID
10212018

Indexing Status
Subject indexing assigned by NLM

MeSH
Adult; Cost-Benefit Analysis; Drug Costs; Drug Therapy /standards /utilization; Female; Gastrointestinal Hemorrhage /epidemiology /etiology /prevention & control; Humans; Male; Middle Aged; Multiple Trauma /complications /economics /surgery; Peptic Ulcer /drug therapy /economics /prevention & control; Practice Guidelines as Topic; Prospective Studies; Risk Factors; Stress, Physiological /complications /drug therapy /economics; Trauma Severity Indices

AccessionNumber
21999000685

Date bibliographic record published
31/01/2004
Date abstract record published
31/01/2004