Clinical significance of a standardized clinical pathway in gastrectomy patients

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 (CP) for gastrectomy patients. The CP employed standardised postoperative management using printed order sets, which included instructions for such matters as medication, diet, removal of the catheter and the mobility of the patients.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised hospitalised patients who underwent distal, total, proximal or partial gastrectomy for either gastric cancer or gastrointestinal stromal tumour. Patients with neo-adjuvant chemotherapy and severe heart failure were excluded from the study.

Setting
The setting was secondary care. The study was conducted at the Nippon Medical School Hospital, Tokyo, Japan.

Dates to which data relate
The effectiveness data come from a single study conducted between January and December 2001. The resource use data related to the same time. The price year was not stated, but it was likely to have been 2001.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The cost data for the single study were collected retrospectively from the same sample as that used in the effectiveness analysis.

Study sample
Power calculations were not used to determine the sample size. The study sample consisted of 85 hospitalised patients who underwent gastrectomy. Of these, 47 (29 males and 18 females) were treated in accordance with the CP and 38 (25 males and 13 females) were treated with traditional methods. The mean age was 63.0 years (standard deviation, SD=12.9) in the CP group and 66.8 years (SD=12.1) in the non-CP group (i.e. control group).
**Study design**
This was a randomised controlled trial (RCT) that was carried out in a single centre. The patients were randomly assigned to either the main building or the east building of the participating hospital, depending on the availability of beds. The duration of follow-up was until hospital discharge. No loss to follow-up was reported.

**Analysis of effectiveness**
The analysis of effectiveness was conducted on an intention to treat basis. The outcomes assessed were:

- the lengths of pre- and postoperative hospital stay;
- the morbidity rate and postoperative complications; and
- the rate of target achievement at 24 hours and at days 4, 7 and 14.

The target after 24 hours was not having to monitor for vital signs using the intensive care nurse-chart every 1 to 2 hours. On the 4th day, the patients were checked to determine whether they could ambulate with the assistance of a nurse. On the 7th day, the patients were checked to see whether they could take liquid meals. On the 14th day, the patients were checked to see if they could be discharged from the hospital.

In terms of baseline characteristics, no significant differences were observed between the CP and control groups in terms of the patients’ age, composition of genders, preoperative complications, anaesthesia risk, stages of gastric cancer and operative procedures.

**Effectiveness results**
The mean length of preoperative stay was 9.0 days (SD=3.2) for the CP group and 12.6 days (SD=6.0) for the control group, (p<0.001).

The mean length of postoperative stay was 18.1 days (SD=9.5) for the CP group and 28.2 days (SD=22.3) for the control group, (p<0.01).

The morbidity rate was 6% for the PC group and 13% for the control group. The difference was not significant.

Three postoperative complications were observed among the CP group (leakage, stenosis and gastro-stasis) versus 5 among the control group (abscess, blind loop syndrome, stenosis, pneumonia and cerebral infarction).

Among the patients who did not have postoperative complications, the length of pre- and postoperative hospital stay was also significantly shorter for the CP group, (p<0.001). The total hospital stay was 25.5 days (SD=4.8) in the CP group and 33.9 days (SD=10.2) in the control group.

However, among the patients who had postoperative complications, the length of hospital stay was not significantly different between the two groups, 50 days (SD=31.2) for the CP group versus 86.8 days (SD=49.3) for the control group.

In terms of target achievement, the CP group was found to be significantly better than the control group at all stages:

- at 24 hours, 87% for the CP group versus 54% for the control group, (p<0.005);
- on day 4, 98% (CP) and 78% (control), respectively, (p<0.05);
- on day 7, 91% (CP) and 68% (control), respectively, (p<0.05); and
- on day 14, 91% (CP) and 50% (control), respectively, (p<0.001).

This trend was also observed among the patients who had postoperative complications.
Clinical conclusions
The CP helped to reduce the length of patients' hospital stay and intensive care monitoring. It also promoted patients to ambulate with assistance and take liquid meals earlier.

Measure of benefits used in the economic analysis
The authors did not develop a summary benefit measure in the economic analysis. Hence, in effect, a cost-consequences study was undertaken.

Direct costs
The direct costs reported were the total medical costs (including medication and examinations) and the costs for medications that were part of the total costs. Discounting was not relevant due to the short period of analysis (less than 2 years). The costs and the quantities were not reported separately. The source of the resource use and cost data was not reported, but it was likely to have been actual data derived from the hospital itself. The price year was not explicitly stated, but it was likely to have been 2001.

Statistical analysis of costs
The cost data were treated stochastically. The differences in costs between the CP and control groups was examined using Student’s t-test or the Mann-Whitney U-test, although it was unclear from the paper which one was actually used.

Indirect Costs
No indirect costs were included.

Currency
Japanese Yen (Y).

Sensitivity analysis
No sensitivity analysis was undertaken.

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

Cost results
The mean total costs were Y1,502,587 (SD=282,489) for the CP group and Y1,932,197 (SD=786,185) for the control group (p<0.001).

The mean costs for medication alone were Y190,339 (SD=112,760) for the CP group and Y270,631 (SD=176,643) for the control group, (p<.001).

The mean daily total costs were Y58,383 (SD=8,575) for the CP group and Y55,651 (SD=15,573) for the control group. This difference was not statistically significant.

Synthesis of costs and benefits
The costs and benefits were not combined. The CP led to a significant reduction in the length of patients' hospital stay (about 10 days) and medical costs (about Y400,000; 22%). At the same time, it led to a significantly earlier recovery of the patients in terms of intake of liquid food and assisted walk. The CP strategy was, therefore, dominant in comparison with traditional practice.
Authors' conclusions
The implementation of a standardised clinical pathway (CP) for gastrectomy patients reduced the length of the patients' hospital stay and the medical costs. Thus, the pathway proved to be a useful tool in optimising postoperative care by including medication management and diet education.

CRD COMMENTARY - Selection of comparators
The choice of the comparator was clearly stated and was the natural alternative to assess the CP. However, a detailed description of what was meant by traditional care would have helped in assessing the relevance of the study to other settings. It is likely that traditional care was associated with a good deal of variability and that this prompted the introduction of the CP.

Validity of estimate of measure of effectiveness
The internal validity of the study is likely to be high as the authors undertook a RCT, although there are some uncertainties about its conduct. For example, the use of power calculations to determine the sample size was not reported (hence the sample may not have been sufficiently large), and the comparator was not clearly detailed. However, the analysis of results was handled credibly, with appropriate statistical tests being employed and measures of variability being reported. A number of effectiveness measures were used in the analysis, which are appropriate in the assessment of this patient domain.

Validity of estimate of measure of benefit
The authors did not use a summary health benefit measure since a cost-consequences analysis was, in effect, conducted.

Validity of estimate of costs
The cost analysis was clearly presented, but there are some limitations in relation to the generalisability of these data to other settings. For example, the source of the costs was not given, the costs and the quantities were not reported separately, and the price year was not specified. Replicating the results in other settings would, therefore, be problematic.

Other issues
The authors did not compare their results with those from other studies. In addition, the generalisability of the study's findings was not assessed through sensitivity analyses or discussion based on clinical practice variations. The authors did not discuss any limitations of their study.

Implications of the study
The findings of the study supported the introduction of this CP in terms of economic and clinical considerations. The authors suggested that future studies should use a more comprehensive CP that includes both preoperative examinations and post-operative evaluations and treatment in their analyses.

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