Efficacy of clinical pathway for the management of mucosal gastric carcinoma treated with endoscopic submucosal dissection using an insulated-tip diathermic knife

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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.

Health technology
Patients with mucosal gastric carcinoma (MGC) were treated with endoscopic submucosal dissection using an insulated-tip diathermic knife (IT-ESD), according to a clinical pathway. Patients who were going to have IT-ESD were examined by endoscopic ultrasonography and the excision range was decided before admission. Respiratory function and an electrocardiogram were checked before IT-ESD, which was performed under informed consent. After the operation, the patients were given three endoscopic examinations according to pre-set criteria. Oral intake was started on the second postoperative day. All patients were given a proton-pump inhibitor (PPI) postoperatively, followed by 4 weeks of oral PPI after discharge. Discharge occurred after the patients could tolerate clear liquids and a regular diet, and a third endoscopic examination after IT-ESD revealed a decrease in the size of the postoperative ulcer. The aim was to achieve discharge on the seventh postoperative day. The comparator intervention was treating the same kind of patient with IT-ESD, but with doctors deciding individually about investigations, diagnoses, treatment and time of discharge. With the comparator treatment, endoscopic ultrasonography and the excision range were decided after admission.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with MGC who were being treated by IT-ESD. The MGC was diagnosed by endoscopic findings or endoscopic ultrasonography. Patients were included if the biopsy specimen obtained from the lesion revealed differentiated carcinoma, the lesion did not have any ulceration, and the tumour was less than 20 mm in diameter. Patients were excluded if they had carcinoma in other organs, if they had severe underlying disease (e.g. heart disease, respiratory disease, liver disease), or a tendency to bleed. Patients on anti-clotting drugs, such as warfarin or aspirin, were included only after a period of discontinuation of the drugs.

Setting
The setting was secondary care. The economic study was carried out in Matsuyama, Japan.

Dates to which data relate
The effectiveness and resource evidence were gathered from 2000 to 2003. The price year was not given.

Source of effectiveness data
The effectiveness data were derived from a single study.
Link between effectiveness and cost data
The costing was carried out retrospectively on the same patient sample that provided both the cost and effectiveness data.

Study sample
No power calculations were reported. There was no sample selection; all patients meeting the inclusion criteria were included in the study sample. The patients in the control group were admitted to the Shikoku Cancer centre between October 2000 and December 2001, while those in the pathway group were admitted to the centre between January 2002 and March 2003. Initially, there were 24 patients in the clinical pathway group and 21 patients in the control group. One patient in each group had to be excluded from the study as it was discovered that they had rectal cancer. Thus, there were 20 patients in the control group and 23 patients in the pathway group. The mean age was 70.5 (+/- 6.7) years (range: 48 - 84) for the overall sample, 69.8 (+/- 7.7) years in the control group and 71.1 (+/- 5.6) years in the pathway group. The male-to-female ratio was 15:5 in the control group and 17:6 in the pathway group.

Study design
This was a single-centred, non-randomised study with historical controls. The patients were not followed up after hospital discharge. The follow-up period was reported to have been 18 months before and after January 2002. No loss to follow-up was reported.

Analysis of effectiveness
The analysis was conducted on an intention to treat basis. The primary health outcomes used were the size of the resected specimen, the proportion of patients who suffered bleeding, and the proportion who suffered from perforation. There was no statistically significant difference between the patient groups at baseline in terms of their demographics and the size of the lesion.

Effectiveness results
The size of the resected specimen was 30.9 (+/- 9.0) mm in the control group and 28.7 (+/- 7.8) mm in the clinical pathway group. The difference was not statistically significant.

The bleeding rate was 45% (n=9) in the control group and 56.5% (n=13) in the clinical pathway group. The difference was not statistically significant.

There were no cases of perforation.

Five patients in the pathway group did not follow the pathway and were discharged on postoperative day 8 or later, resulting in a variance rate of 21.7%. They started eating late as a result of bleeding.

Clinical conclusions
There were no statistically significant differences in the health outcomes between the patients treated before the pathway was introduced and those treated after its introduction.

Measure of benefits used in the economic analysis
No summary measure of benefits was produced. In effect, the authors carried out a cost-consequences analysis.

Direct costs
No discounting was carried out as the costs were incurred during less than one year. The total costs from the time the gastric carcinoma was diagnosed to the time of discharge were given. The only sub-category of costs given was that of hospital costs. The quantities and the costs were not analysed separately. The costs were estimated using data obtained
from the hospital. No price year was given.

**Statistical analysis of costs**
No statistical analysis of the costs was carried out.

**Indirect Costs**
No indirect costs were included.

**Currency**
Japanese yen (Y).

**Sensitivity analysis**
No sensitivity analysis was carried out.

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

**Cost results**
The mean hospital cost was Y514,000 (+/- 117,000) in the control group and Y407,000 (+/- 76,000) in the clinical pathway group, (p<0.001).

The mean total cost was Y530,000 (+/- 106,000) in the control group and Y439,000 (+/- 75,000) in the clinical pathway group, (p<0.01).

The costs of adverse events were dealt with in the costing.

**Synthesis of costs and benefits**
The costs and benefits were not combined as the study was a cost-consequences analysis.

**Authors' conclusions**
The patients in the clinical pathway group had similar health outcomes and lower treatment costs to those treated before the pathway was introduced. Therefore, the clinical pathway and the standardisation of treatment for mucosal gastric carcinoma (MGC) treated with endoscopic submucosal dissection using an insulated-tip diathermic knife (IT-ESD) proved effective for treating patients with MGC and for minimising the length of hospitalisation without compromising patient care.

**CRD COMMENTARY - Selection of comparators**
The choice of the comparator (no clinical pathway) was justified as having represented current practice in the past. You should decide if the comparator represents current practice in your own setting.

**Validity of estimate of measure of effectiveness**
The source of the effectiveness data was a single study. The study design was a non-randomised trial with historical controls. It would have been better to have used a randomised trial with concurrent controls. The study sample was representative of all patients meeting the inclusion criteria since there was no sample selection. The patient groups were shown to be comparable at analysis. The analysis of effectiveness was handled credibly, but there was no follow-up
after hospital discharge and this might have affected the analysis.

**Validity of estimate of measure of benefit**
The authors did not derive a summary measure of health benefit. The analysis was one of cost-consequences.

**Validity of estimate of costs**
From the cost perspective adopted (i.e. the health system), it appears that all the relevant categories of costs have been included. However, as there was no detailed breakdown of the costs it is impossible to be sure. The costs and the quantities were not reported separately, and this may hinder the reproducibility of the results. The resource use quantities were taken from a single study, while the prices were taken from the authors’ setting. No other sources were used for prices. No statistical, sensitivity or any other kind of analysis of the quantities or prices was carried out. The year to which the prices referred was not stated, and this may hinder the generalisability of the results.

**Other issues**
The authors made appropriate comparisons of their results with those from other studies that assessed alternative treatments. The generalisability to other settings was not addressed. The authors did not present their results selectively, but the absence of follow-up after hospital discharge means that the authors’ conclusions do not completely reflect the scope of the analysis. The authors did not report any limitations of their study.

**Implications of the study**
The authors recommended the introduction of a clinical pathway, similar to the one adopted in their hospital, as a way of reducing costs without reducing the quality of treatment. They considered changing the pathway studied in this paper by reducing the number of days before surgery from 2 to 1, having the patients discharged on day 6 rather than day 7 and reducing the number of postoperative endoscopies from 3 to 2.

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