The mastectomy clinical pathway: what has it achieved?

Santoso U, Iau P T C, Lim J, Koh C S, Pang Y T

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
Women with breast cancer who were going to have a mastectomy had their care decided by a 'clinical pathway'. This was devised by hospital staff on the basis of information gained by a literature search. The aim of the pathway was to provide the best care and to standardise the care across all patients.

The clinical pathway had several characteristics. The aim was for an early postoperative discharge, defined as discharge by the 4th postoperative day (POD). Patient education was given a high priority and started at the initial consultation at which consent for surgery was given. The breast care sister was also involved from this point, and was very important in giving practical instructions in drain and wound care. Early ambulation was encouraged after anaesthesia and physiotherapy was started on the first POD.

The patients were told that they would be discharged from hospital when they satisfied a number of criteria. These were that they should be ambulatory, capable of drain and wound care, have adequate pain control and no special nursing requirements.

Patients receiving treatment governed by the clinical pathway were compared with those of an earlier time period when no pathway had been devised or put into practice, when there was no explicit target for early discharge, and treatment between the patients was not standardised.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised women with breast cancer who had been admitted for elective mastectomy. Patients with bilateral mastectomy were excluded, as were patients admitted for other unrelated clinical conditions and those with any kind of immediate breast reconstruction.

Setting
The setting was secondary care (a hospital). The economic study was carried out in Singapore.

Dates to which data relate
The effectiveness evidence was gathered from March to October 2000 for historical controls, and from March to October 2001 for pathway patients. The resource use related to March to October 2000, and March to October 2001. No price year was given.

Source of effectiveness data
NHS Economic Evaluation Database (NHS EED)
Produced by the Centre for Reviews and Dissemination
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The effectiveness data were derived from a single study.

**Link between effectiveness and cost data**
The costing was carried out on the same sample of patients as that used in the effectiveness analysis. The costing was retrospective for the control group patients, but it was unclear whether it was conducted prospectively for the patients in the pathway group.

**Study sample**
No power calculations to determine the sample size were carried out. There was no sample selection. All the women who satisfied the inclusion criteria over the time period were studied. There were 69 patients in the pre-pathway control group and 83 in the pathway group.

**Study design**
This was a non-randomised trial with historical controls.

**Analysis of effectiveness**
The basis of the analysis was intention to treat. The primary health outcomes used were postoperative complications occurring within 30 days of surgery and unscheduled readmissions within 15 days. The complications were broken down into seroma formation, haemotoma, necrosis and wound infection. The authors noted all "variances" in the pathway group, which meant describing all cases that had not gone according to plan. The groups were shown to be comparable in terms of age, class and prevalence of concomitant chronic disease.

**Effectiveness results**
There were 3 (3.61%) unscheduled readmissions in the pathway group (2 for an infected seroma and one for post-mastectomy fever) and 2 (2.91%) in the non-pathway group (both for post-mastectomy fever).

The complication were as follows:

- there were 20 cases (28.99%) of seroma in the pre-pathway group and 24 (28.92%) in the pathway group;
- there were 6 cases (8.70%) of haemotoma in the pre-pathway group and 2 (2.41%) in the pathway group;
- there were 0 cases of necrosis in the pre-pathway group and 2 (2.41%) in the pathway group; and
- there were 3 (4.35%) wound infections in the pre-pathway group and 2 (2.41%) in the pathway group.

There was no statistically significant difference in the complication and readmission rates between the two groups, (p=0.805).

The recording of "variances" by the authors showed that 10 patients in the pathway group could not be discharged on the target day of 4th POD. This was because of the lack of psychosocial support at home (5), complications (2), co-morbidities (2), and nursing home regulations that did not allow return with drains (1).

**Clinical conclusions**
The authors argued that the introduction of the pathway improved patient care. The quantitative data presented by the authors showed no difference in clinical outcomes after the pathway.

**Measure of benefits used in the economic analysis**
No summary measure of benefit was used. A cost-consequences analysis was therefore carried out.
Direct costs
Discounting was not carried out, but this was appropriate as the costs for each patient were incurred in less than one year. The quantities and the costs were not analysed separately. The length of stay in hospital was used as a proxy for a measure of quantities of resources used. The hospital costs were measured using hospital charges. The costs were taken from the data on the patients in the study. The year of the pre-pathway data was 2000 and the year of the pathway group was 2001. No common price year was used.

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

Indirect Costs
No indirect costs were calculated.

Currency
The authors measured and reported the costs in dollars, presumably Singapore dollars (SG$).

Sensitivity analysis
No sensitivity analysis was carried out.

Estimated benefits used in the economic analysis
No summary health benefit was used. A cost-consequences analysis was carried out which showed no statistically significant differences between the two groups of patients. See the 'Effectiveness Results' section.

Cost results
The mean cost per patient was SG$5,050 before the clinical pathway was introduced and SG$4,406 after its introduction, (p=0.014).

Synthesis of costs and benefits
Not relevant.

Authors’ conclusions
The clinical pathway improved patient care and reduced the costs.

CRD COMMENTARY - Selection of comparators
The choice of the comparator, practice in the hospital before the clinical pathway was introduced, was implicitly justified since this was a study of the effects of introducing a change in practice. The authors did not describe the practice before the introduction of the pathway. However, it can be deduced that there was considerable variation in care between the treatments and there was far less patient education.

Validity of estimate of measure of effectiveness
The effectiveness data were obtained from the hospital in which the study was carried out. The analysis used a non-randomised study with historical controls. This meant that, although there were several good aspects of the study, the possibility existed that other factors apart from the introduction of the clinical pathway could have occurred between the two time periods. No sample selection took place so the study sample was representative of the study population.
The patient groups were shown to be comparable at analysis. Although the analysis of the effectiveness evidence was handled credibly, the study examined effectiveness evidence for only 30 days after surgery and did not include any psychological assessments or quality of life measurements of the patients.

**Validity of estimate of measure of benefit**
The authors did not derive a summary measure of health benefit (see 'Validity of the estimate of measure of effectiveness').

**Validity of estimate of costs**
The costs were not broken down into prices, and the quantities and hospital charges were used as a measure of costs. All the costs came from the hospital, which makes it difficult for decision-makers elsewhere to make good use of the cost information. The authors gave an incomplete picture of the costs in other ways. For example, they did not use a common price year and did not explicitly report the currency in which the costs were calculated.

The most important omission in terms of the costs was the fact that the indirect costs were not calculated for the patient and carers. As the clinical pathway entails less hospital care and more care at home, it is surely important that these should be calculated. For a societal perspective (of relevance to the UK NHS), the indirect costs would be a necessary aspect of future analyses.

No statistical or sensitivity analyses of the prices and quantities were carried out.

**Other issues**
The authors compared their work with the findings of other authors. However, they did not address the issue of the generalisability of their results to other settings. The authors are aware that their study (unlike those carried out in other countries) did not address the issue of patient satisfaction or well-being under the clinical pathway, but they did not appear to be aware of the consequences for the family or carers. Also, they did not address the incompleteness of the data they have given on the costs, and how this limits the usefulness of the results for those in other settings.

**Implications of the study**
The findings of the study support the authors’ view that the costs were lower in Singapore after a clinical pathway was introduced for breast cancer patients undergoing mastectomy. This agrees with the findings of studies in other countries cited by the authors. The authors also found that clinical outcomes were not harmed by the shorter period in hospital after surgery, which was introduced as a consequence of the clinical pathway. However, the authors agree that their research findings would have been more useful had patient satisfaction been included in the study. As one of their stated concerns was the cultural difference between Singapore and other countries where clinical pathways have been assessed, it is rather odd that they did not do this.

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