Implementation and evaluation of a clinical pathway for TRAM breast reconstruction

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
Assessment of a clinical pathway to improve efficiency and reduce variation in the postoperative care of patients undergoing transverse rectus abdominis musculocutaneous (TRAM) breast reconstruction. A multidisciplinary team of clinicians, including a plastic surgeon, clinical nurse specialists, staff nurses, a pharmacologist, and hospital administrators, was assembled to devise and initiate the TRAM reconstruction clinical pathway. All aspects of postoperative care were addressed in the clinical pathway, including fluid and electrolyte management, pain control, pulmonary care, physical activities, diet, pulmonary embolism prophylaxis, antibiotics, catheter care, utilisation of blood products, laboratory testing, patient teaching, psychological support services, discharge planning, and follow-up care.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients undergoing TRAM breast reconstruction.

Setting
Hospital. The economic study was carried out in Michigan, USA.

Dates to which data relate
Effectiveness and resource use data corresponded to patients treated between 1 September 1994 and 31 March 1996 for the control group (before the implementation of the pathway) and between 1 April 1996 and 1 June 1997 for the experimental group (after the implementation of the pathway). The price year was 1997.

Source of effectiveness data
The evidence for the final clinical outcomes was derived from a single study.

Link between effectiveness and cost data
Costing was retrospectively undertaken on the same patient samples as those used in the effectiveness analysis.

Study sample
Power calculations were not used to determine the sample size. The study sample consisted of 40 patients in the control group with a mean age of 44.7 years, and 29 in the experimental group with a mean age of 46.8 years.
Study design
This was a retrospective cohort study, carried out in a single centre. The duration of the follow-up was 30 days after surgery. Loss to follow-up was not reported. Hospital charts were reviewed to obtain data on length of stay and postoperative complications.

Analysis of effectiveness
The principle used in the analysis of effectiveness was treatment completers only. The health outcomes were length of stay (LOS) and complications occurring within 30 days of surgery (as an indicator of postoperative quality of care). The study groups were comparable in terms of age and the distribution between immediate and delayed reconstruction, but not with respect to the distribution of free versus pedicle and unilateral versus bilateral procedures; a greater percentage of pedicle and unilateral TRAMs occurred in the post-pathway group. The effects of potential confounders were adjusted using analysis of covariance.

Effectiveness results
Length of stay decreased significantly from 6.0 days in the control group to 5.2 days in the experimental group, \(p=0.026\). Rates of early complications between the two groups were virtually identical at 0.28.

Clinical conclusions
Although resource utilisation decreased significantly after pathway implementation, the incidence of early complications did not change, suggesting that quality was not compromised with use of the pathway.

Measure of benefits used in the economic analysis
No summary benefit measure was explicitly identified in the economic analysis. However, since the study groups were equivalent in terms of complications occurring within 30 days of surgery (as an indicator of postoperative quality of care), the economic study appears to have proceeded as a cost-minimisation analysis.

Direct costs
Costs were not discounted due to the short time frame of the cost analysis. Quantities were reported separately from the costs. Cost items were reported separately. Cost analysis covered the postoperative care costs of supplies, pharmaceuticals, and laboratory tests. The perspective adopted in the cost analysis was not explicitly specified. Cost analysis was conducted based on both charge data and true costs. Billing data for postoperative care were collected from the medical centre finance department. The Relative Value System was used to gather financial data for the various time periods in the study. Relative value units have been assigned to each of the medical centre's fee codes. Charge data were adjusted for inflation. The price year was 1997. Because the TRAM pathway covered only postoperative care, intraoperative charges and costs were not included in the cost comparisons.

Statistical analysis of costs
Student's t test was used to compare the groups in terms of charges and relative value units. In the comparison of charges and relative value units, analysis of covariance was used to adjust for the effects of potential confounders. Variability was investigated using comparison of variances by means of the F-test in nonoperative hospital charges and nonoperative relative value units.

Indirect Costs
Indirect costs were not included.

Currency

US dollars ($).

**Sensitivity analysis**
A sensitivity analysis was not conducted.

**Estimated benefits used in the economic analysis**
Rates of early complications between the two groups were virtually identical at 0.28.

**Cost results**
The total postoperative charges was $8,587 in the pre-implementation period versus $7,744 in the post-implementation period, (p=0.196). Total postoperative relative value unit utilisation declined from 1,686 to 1,104, (p=0.0004).

**Synthesis of costs and benefits**
Costs and benefits were not combined since with equal effectiveness of the alternatives in terms of early postoperative complications, the economic analysis was cost-minimisation.

**Authors' conclusions**
Implementation of a clinical pathway for TRAM breast reconstruction achieved the set objectives of reducing resource use without increasing complication rates. This experience has served as a model for the development and implementation of additional pathways for plastic surgery procedures in the study hospital.

**CRD COMMENTARY - Selection of comparators**
Routine care before the implementation of the clinical pathway, as the comparator, was justified. This allowed the active value of the clinical pathway to be evaluated.

**Validity of estimate of measure of effectiveness**
The internal validity of the effectiveness results cannot be guaranteed due to the retrospective nature of the study design. However, the comparability of the study groups in terms of age and the distribution between immediate and delayed reconstruction, and adjustments made for the effects of known potential variables strengthened the internal reliability of the effectiveness results. The degree to which the patient sample was representative of the study population cannot be objectively assessed due to lack of adequate information regarding the inclusion and exclusion criteria adopted in the study. The authors acknowledged that using only the complication rate as a measure of quality of care was one of the limitations of the study.

**Validity of estimate of measure of benefit**
The authors utilised complication rate and length of stay as proxies for health benefit. The economic analysis was essentially a cost-minimisation design.

**Validity of estimate of costs**
Quantities were reported separately from the costs and adequate details of the methods of cost estimation were given. Cost analysis was based on both charge data and true costs, as measured by using relative value units. The effects of alternative procedures on indirect costs were not addressed. Statistical analysis was performed on both resource use data and charge/cost data. The effects of potential confounders on charge/cost data were evaluated and variability in resource use and charge/cost data were investigated. Cost results may not, however, be generalisable to other countries or settings due to the lack of sensitivity analysis.
Other issues
The authors’ conclusion appears to be justified. The issue of generalisability to other settings or countries was not addressed, although some comparisons were made with other studies. The authors acknowledged that the limited scope of the clinical pathway to postoperative care was a shortcoming of the study. The degree to which the study sample was representative of the study population was not explicitly addressed.

Implications of the study
In future studies, the authors advocate using more comprehensive assessments, including patient satisfaction, hospital readmission rates, health status, and quality of life. It was also reported that efforts are currently under way to revise and expand the TRAM reconstruction clinical pathway to encompass preoperative, intraoperative, and postoperative care. Additional clinical pathways are being implemented for patients undergoing pressure sore repairs and free tissue transfers.

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