Randomized clinical trial of no wound drains and early discharge in the treatment of women with breast cancer


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 technology studied was the suturing of flaps with no drain (SF-ND; i.e. multiple parallel rows of 3/0 undyed Vicryl sutures, Ethicon, Edinburgh, UK; 3/0 PDS, Ethicon) in women undergoing surgery for breast cancer. SF-ND was combined with a level 2 axillary clearance and early discharge from hospital.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised women undergoing surgery for primary breast cancer. Patients were excluded if they were pregnant, unsuitable for early discharge home because of extreme anxiety or poor social support, or unable to fully participate due to any serious underlying medical condition.

Setting
The setting was hospital. The economic study was carried out in the UK.

Dates to which data relate
The dates to which effectiveness and cost data related were not given. The price year was 1999.

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

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample as that used in the effectiveness study.

Study sample
The sample size was determined in the planning phase of the study to assure a certain power (probably 95%). The authors reported that two parallel randomised trials were performed, one for women undergoing breast-conserving surgery and the other for women undergoing mastectomy, in order to look for differences in the proposed alternatives that were not due to surgical morbidity. The initial sample size proposed for each of the parallel randomised trials was 200 women (100 randomised to SF-ND and 100 to WD).
In total 496 patients were eligible. From these, 379 were randomised, either to SF-ND or to WD. The WD group was composed of 190 patients (from whom 96 underwent mastectomy and 94 had breast-conserving surgery), and the SF-ND group was composed of 185 patients (with 94 patients undergoing mastectomy and 91 having breast-conserving surgery). The authors reported that 18 patients in the SF-ND group had to receive WD because of surgical intra-operative oozing. Four patients, among the 379 eligible women, withdrew immediately before surgery, and no reasons were given for these withdrawals.

**Study design**

This was a prospective randomised trial, consisting of two parallel randomised trials. The justification given by the authors for this approach was that, in case of there being poor differentiation between groups regarding morbidity, the differences found between the proposed alternatives may have been due to differences in surgical morbidity. The study was carried out in a single centre. The subjects were allocated using block randomisation. The duration of follow-up was 1 year. No loss to follow-up was reported.

**Analysis of effectiveness**

The analysis of effectiveness was based on intention to treat.

The primary health outcomes assessed in the effectiveness analysis were: length of hospital stay and the reduction in the length of stay for women undertaking SF-ND in comparison with those in the WD group; the number (and percentage) of women with wound infection; the number (and percentage) of women with seroma formation; the volume in ml of seroma fluid aspirated; the change in degrees in shoulder abduction with regard to the baseline value, and the mean overall difference in shoulder abduction; psychological morbidity, measured as the number of patients with significant distress after operation, at 3 months, at 6 months and at 12 months.

Patients undergoing SF-ND were discharged after 48 hours if they were fully mobile, able to perform common activities of daily living, able to tolerate a full diet, required only analgesia and reported to be able to manage at home. WD patients were discharged home on drain removal. Shoulder abduction was measured by means of a goniometer. Distress was measured by means of the General Health Questionnaire (GHQ-28), considering as the initial cut-off point the one indicating significant distress. It was stated that the GHQ-28, the Mental Adjustment to Cancer (MAC) scale, the Illness Perception Questionnaire (IPQ) and the Eysenck Personality Scales (EPS), were given to the patients at the first post-operative visit, and at 3, 6 and 12 months in order to evaluate psychological morbidity of the patients. However, results were only reported for the GHQ-28 and the EPS. The authors’ justification to exclude the other outcomes was that there was no evidence of difference between WD and SF-ND patients. The authors reported that the groups were comparable at analysis in terms of age, EPS and shoulder movement, although they did not report any statistical test to show that the differences were non-significant.

**Effectiveness results**

The results for women undergoing mastectomy were as follows (standard deviations in brackets):

The length of hospital stay was 5.59 days (SD 1.05) for WD patients, and 4.18 days (SD 1.51) for SF-ND patients.

There was a reduction in the length of stay for women undertaking SF-ND in comparison with those in the WD group of 1.41 days (95% CI: 1.04 - 1.78; p<0.001).

The number (and percentage) of women with wound infection was 10 (10%) in the WD group, and 10 (11%) among the SF-ND patients.

In the WD group, 52 patients had seroma formation (55%), and in the SF-ND group, 57 (61%) patients had seroma formation.

The volume of seroma fluid aspirated (standard errors in brackets) was 213 ml (41) for WD patients, and 184 ml (28) for SF-ND patients.
The change in the shoulder abduction with regard to the baseline value (standard errors in brackets) was -27.9 degrees (2.6) for WD patients versus -29.3 degrees (2.1) for SF-ND patients after the operation; -6.9 degrees (2.0) for WD patients versus -9.6 degrees (2.3) for SF-ND patients at 3 months; -2.8 degrees (1.9) for WD patients versus -8.8 degrees (2.1) for SF-ND patients at 6 months; and -0.1 degrees (2.3) for WD patients versus -3.2 degrees (2.4) for SF-ND patients at 12 months. The mean overall difference in shoulder abduction in favour of the WD patients was 2.4 degrees (95% CI: -0.8 - 6.1; p=0.13).

The numbers of patients presenting significant distress were:

for WD patients - after operation 31 (38%); at 3 months 27 (39%); at 6 months 18 (25%); and at 12 months 12 (17%); and

for SF-ND patients - after operation 30 (39%); at 3 months 30 (42%); at 6 months 21 (33%); and at 12 months 20 (30%).

The results for women undergoing breast-conserving surgery were (standard deviations are given in brackets):

The length of hospital stay was 4.86 days (SD 1.16) for WD patients, and 3.31 days (SD 0.96) for SF-ND patients. There was a reduction in the length of stay for women undertaking SF-ND of 1.55 days (95% CI: 1.24 - 1.86; p<0.001) in comparison with those in the WD group.

The number (and percentage) of women with wound infection was 9 (10%) in the WD group, and 16 (18%) among the SF-ND patients.

In the WD group, 46 patients had seroma formation (51%), and in the SF-ND group, 41 (47%) patients had seroma formation.

The volume of seroma fluid aspirated (standard errors in brackets) was 122 ml (24) for WD patients, and 166 ml (19) for SF-ND patients.

The change in the shoulder abduction with regard to the baseline value (standard errors in brackets) was -23.0 degrees (2.0) for WD patients versus -24.4 degrees (2.3) for SF-ND patients after the operation; -10.7 degrees (1.9) for WD patients versus -6.4 degrees (2.3) for SF-ND patients at 3 months; -5.5 degrees (1.5) for WD patients versus -3.8 degrees (2.0) for SF-ND patients at 6 months; and -2.2 degrees (1.8) for WD patients versus -0.3 degrees (1.7) for SF-ND patients at 12 months. The difference in the mean overall shoulder abduction in favour of the WD patients was 0.7 degrees (95% CI: -2.1 - 3.6; p=0.61).

The numbers (and percentages) of patients with significant distress were:

in the WD group - after operation 34 (43%); at 3 months 27 (40%); at 6 months 21 (31%); and at 12 months 15 (22%); and

in the SF-ND group - after operation 30 (38%); at 3 months 29 (39%); at 6 months 15 (22%); and at 12 months 11 (16%).

Clinical conclusions
There was a significant reduction in the length of hospital stay for patients undergoing SF-ND in both parallel trials (mastectomy and breast-conserving surgery groups). Among the patients who underwent breast-conserving surgery, there was a higher percentage of patients in the WD group presenting significant distress in comparison with the SF-ND patients, although the difference was not shown to be statistically significant. After an initial deterioration in shoulder mobility after surgery, all patients returned to near-normal shoulder mobility after 12 months, with no significant differences among the groups. Overall, the number of patients presenting significant distress in both groups (WD and SF-ND), and in both trials (mastectomy and breast-conserving surgery), decreased over time.
Measure of benefits used in the economic analysis
A cost-consequences analysis was performed. Therefore, no summary measure of benefit was used in the economic analysis.

Direct costs
Some of the resource quantities were reported separately from the costs (i.e. length of operation and length of stay). Although the authors reported that two perspectives were adopted (the health service and the patients perspectives), the only costs that were actually reported were those associated with the consumables used in theatre. The authors stated that they wished to assess the costs to the patients and their families in terms of out-of-pocket expenses, although no data about these costs were provided. Standardised data collection forms, medical records, diaries completed by patients and questionnaires were used as source of the direct cost data. Therefore, the estimation of the costs was based on actual data. No discounting appears to have been performed, which was appropriate given that the costs were incurred over a period shorter than 2 years. The price year was 1999.

Statistical analysis of costs
No statistical analysis of costs was reported.

Indirect Costs
The authors reported that self-completed questionnaires were used to estimate the costs to patients and their families of disruption to normal activities. These costs may have included lost income or lost productivity, although no additional information was provided.

Currency
UK pounds sterling ( £ ).

Sensitivity analysis
No sensitivity analysis was reported.

Estimated benefits used in the economic analysis
The reader is referred to the 'Effectiveness Results' section, reported above.

Cost results
The only cost results reported by the authors were the costs of consumables used in theatre. These were lower for SF-ND patients when compared to WD patients (15.86 versus 13.08).

The authors reported that there were no differences between the groups in the costs of primary and secondary care in the 3-month period following surgery, or in the costs to patients and their families regarding out-of-pocket payments and disruption to normal activity. However, results were not given and statistical analyses were not provided.

Synthesis of costs and benefits
Not applicable due to the cost-consequences approach.

Authors' conclusions
The authors concluded that the early discharge among SF-ND patients as a consequence of avoiding wound drainage resulted in no difference in surgical or psychological morbidity. No conclusions about the specific cost results obtained for the interventions under study were given.
CRD COMMENTARY - Selection of comparators
A justification was given for the comparator used, namely that WD was the standard practice after surgery for primary breast cancer in the authors' setting. You, as a user of the database, should decide if this is a widely used health technology in your own setting.

Validity of estimate of measure of effectiveness
The analysis was based on a prospective randomised trial, which was appropriate for the study question. Moreover, a positive aspect of the study was that two parallel trials were considered at analysis, differentiating between women undergoing mastectomy and women undergoing breast-conserving surgery, in order to observe differences between the alternative interventions not related to surgical morbidity. The study sample appears to have been representative of the study population. The authors stated that the patient groups were comparable at analysis in terms of age, EPS and shoulder movement, although no statistical tests to support this contention were reported. Some statistical analyses were undertaken to study whether the effectiveness results were significantly different across groups. Block randomisation was used in the allocation of patients to each of the alternatives. The advantage of this was that the number of patients between groups was kept as close as possible. Some patients in the SF-ND group had to undergo WD because of surgical intra-operative oozing, which hinders the interpretation of the study findings.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefit. The analysis was therefore categorised as a cost-consequences study.

Validity of estimate of costs
Although the authors stated that two perspectives were considered at analysis (that of the health service and that of the patient), no information was provided regarding the total costs. The only costs reported in the study were the costs of consumables used in theatre, which is a very limited perspective to consider at analysis. Some resource quantities were reported separately from the costs. The price year was given, but not the dates to which cost data related. No statistical analyses of costs were reported. These factors introduce uncertainty into the reliability of the conclusions.

Other issues
The authors made comparisons of their findings with those from other studies but the issue of generalisability to other settings was not addressed. It is not clear whether the study reflects the scope of the analysis because the limited cost data reported did not correspond with the perspective adopted and, moreover, did not permit a clear conclusion to be drawn regarding the most appropriate intervention.

Implications of the study
The study may have relevance in that it shows that there are no significant differences in the health outcomes obtained by both interventions, SF-ND and WD. The main significant difference is in the length of hospital stay, which is shorter for SF-ND. However, caution should be exercised due to the lack of comprehensive evidence regarding cost data, which hinders any firm conclusion as to which alternative is the most cost-effective.

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