Costs and benefits of a one stop clinic compared with a dedicated breast clinic: randomised controlled trial


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 one-stop clinic (OSC) for assessing women with suspected breast cancer. The OSC involved a mammogram, which could be followed by an ultrasonography assessment by a consultant surgeon and then aspiration cytology. Finally, the consultant surgeon reassessed the patients and discussed their treatment. The entire process took place on the same day.

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised women with suspected breast cancer.

Setting
The setting was a hospital. The economic study was carried out at Withington Hospital, Manchester, UK.

Dates to which data relate
The effectiveness data and cost data were collected between April 1995 and November 1996. The price year was 1998.

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

Link between effectiveness and cost data
In addition to the sample population included in the effectiveness analysis, other women who did not participate in the study were considered for the analysis of the costs. The cost data appears to have been collected prospectively.

Study sample
Power calculations were performed to determine the sample size, due to cancelled clinics and two unexpected sources of attrition a termination date was set to achieve 80% power. The study had 79% power to exclude a 15% difference. All women (aged 35 years or over) who were admitted to the hospital for urgent assessment of a breast lump during the study period were analysed. The study sample appeared representative of the study population. A total of 695 appointments were offered to 670 women, of whom 633 (94.5%) attended for their appointments. Subsequently, 94 women were excluded because they were not interviewed before assessment (69 women; 10.9%), they were ineligible
(19 women; 3.0%), or they had reading difficulties (6 women; 0.9%). It was necessary for all the women analysed to fill in some questionnaires in order to assess their levels of anxiety. A further 61 patients (24 from the OSC group and 37 from the DBC group) refused to participate in the study. The final study sample comprised 478 women, of which 267 (55.9%) were randomised to the OSC group and 211 (44.1%) to the DBC group. A total of 59 patients were excluded from the OSC group because of withdrawal (1), no baseline assessment (1), or no post-intervention assessment (57). Within the DBC group, a total of 58 patients were excluded because of either withdrawal (1) or the unavailability of a post-intervention assessment (57).

**Study design**
This was a randomised controlled trial carried out in a single centre. The duration of follow-up was 12 months. The women were allocated randomly to the study groups and were informed about the study. The women could decide not to participate, or they could change to the DBC group if they were allocated initially to the OSC group. Randomisation was conducted using a balanced block design stratified by consultant and generated by an independent statistician.

**Analysis of effectiveness**
The analysis of effectiveness was based on intention to treat, and patients were analysed in their assigned groups. The primary health outcomes assessed in the analysis for both strategies (OSC and DBC) were:

- the median number (and range) of days between the first attendance and diagnosis;
- the number and percentage of women who had either one, two, or three or more visits before diagnosis was made;
- the number and percentage of women assessed by a consultant or senior registrar;
- the number and percentage of women undergoing a mammography, an ultrasonography, a fine-needle aspiration cytology, a core biopsy, an aspiration of cyst, or an excision biopsy;
- the number and percentage of women diagnosed as having no abnormality detected, benign lump, cyst, other benign condition, ductal carcinoma in situ or atypical, or cancer;
- the mean number of visits after diagnosis;
- the reduction in mean anxiety scores for OSC patients in comparison with DBC patients at 24 hours, 3 weeks and 3 months; and
- the percentage of patients with anxiety at 3 weeks and at 3 months.

The anxiety scores were measured using the state-trait anxiety inventory and the anxiety subscale of the hospital anxiety depression scale (see Other Publications of Related Interest).

The authors reported that the baseline characteristics were similar across the groups. However, no evidence to support this statement was reported.

The authors stated that the women who refused to participate in the study were more likely to have been allocated to the DBC group (15% versus 8% in the OSC group; p=0.021). They were also more likely to have cancer (30% versus 13% for participants; p=0.002), and to be older (mean age: 56 versus 49 years for the participants; p<0.0001). The baseline anxiety scores were similar for women completing and not completing the follow-up questionnaires.

**Effectiveness results**
The median number of days between the first attendance and diagnosis was significantly higher for the DBC (8 days, range: 0 - 190) than for the OSC (0 days; range: 0 - 85), (p<0.0001).

In total, 243 women (91.0%) in the OSC and 104 (49.3%) in the DBC made one visit before diagnosis was made.
There were 19 women (7.1%) in the OSC and 78 (37.0%) in the DBC who made two visits before a diagnosis was made. Finally, there were 5 women (1.9%) in the OSC and 29 (13.7%) in the DBC who made at least three visits before a diagnosis was made. The differences between both groups were statistically significant (p<0.0001).

The number of women assessed by a consultant or senior registrar was 253 (94.8%) in the OSC and 131 (62.1%) in the DBC. The difference between both groups was statistically significant (p<0.0001).

A total of 261 women (97.8%) underwent a mammography in the OSC, compared with a significantly smaller number (176 women; 83.4%) in the DBC, (p<0.0001).

The number of women undergoing ultrasonography was also statistically significantly higher for the OSC group (236 women; 88.4%), compared with the DBC group (37; 17.5%), (p<0.0001).

The numbers of women who underwent other diagnostic procedures were:
for fine-needle aspiration cytology, 124 (46.4%) in the OSC group versus 92 (43.6%) in the DBC group, (p=0.6);
for core biopsy, 12 (4.5%) in the OSC group versus 9 (4.3%) in the DBG group, (p=1);
for aspiration of cyst, 61 (22.8%) in the OSC group versus 55 (26.1%) in the DBC group, (p=0.48); and
for excision biopsy, 14 (5.2%) in the OSC group versus 9 (4.3%) in the DBC group, (p=0.78).

The numbers of women diagnosed with following conditions were:
no abnormality, 40 (15.0%) in the OSC group versus 49 (23.2%) in the DBC group;
benign lump, 83 (31.2%) in the OSC group versus 65 (30.8%) in the DBC group;
cyst, 81 (30.3%) in the OSC group versus 55 (26.1%) in the DBC group, (p=0.23);
other benign condition, 20 (7.5%) in the OSC group versus 16 (7.6%) in the DBC group;
ductal carcinoma in situ or atypical, 4 (1.5%) in the OSC group versus 1 (0.5%) in the DBC group; and
cancer, 39 (14.6%) in the OSC group versus 25 (11.8%) in the DBC group.

The mean number of visits after diagnosis was 1.18 in the OSC and 1.05 in the DBC group. The difference between the groups was not statistically significant, (p=0.44).

The reductions in mean anxiety scores for OSC patients, compared with DBC patients were -5.7 (range: -8.4 - -3.0) at 24 hours, -0.2 (range: -1.0 - 0.5) at 3 weeks, and -0.5 (range: -1.3 - 0.3) at 3 months.

The proportion of patients with anxiety at 3 weeks was 41.8% (87 patients) in the OSC group, and 48.4% (74 patients) in the DBC group. The proportion of patients with anxiety at 3 months was 42.7% (94 patients) in the OSC group, and 47.5% (75 patients) in the DBC group.

**Clinical conclusions**
Patients in the OSC group were more likely to be initially assessed by a consultant or a senior registrar. They were also more likely to have a mammogram or ultrasonography at diagnosis, and to be given a diagnosis at their first visit. The anxiety scores were significantly smaller for OSC patients at 24 hours, but not at 3 weeks or 3 months. Therefore, the OSC patients showed benefits in terms of anxiety scores, but only in the very short term.

**Measure of benefits used in the economic analysis**
No summary measure of benefit was used in the economic analysis. A cost-consequences analysis was therefore...
performed.

Direct costs
Some of the resource quantities were reported separately from the costs. In particular, the number of minutes imputed to staff (e.g. surgical time, nursing time or consultant radiologist time) and the number of specialists needed for the alternative strategies. The direct costs reported were those of the NHS. In particular, these related to the staff costs for assessment and the costs of the investigations. The staff costs included the first clinic visit (surgical, pathological, radiological, nursing, and administrative and porterage staff), other assessment clinic visit costs, and post-diagnosis clinic visit costs. The investigation costs included mammography, ultrasonography, fine-needle aspiration cytology, core biopsy, excision biopsy, and those investigations undertaken during the 12-month follow-up. In order to estimate the costs, it was assumed that the pathology staff could spend half their time on other activities while awaiting specimens. The costs were estimated using data from the South Manchester University Hospitals Trust (1998). Discounting was not carried out, which was appropriate given that the costs were incurred over less than 2 years. The costs reported were the average costs. The price year was 1998.

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

Indirect Costs
The indirect costs were not reported.

Currency
UK pounds sterling (€).

Sensitivity analysis
A one-way sensitivity analysis was undertaken to analyse the variability in the data. The authors studied the change in the costs assuming that a consultant initially assessed all patients in both groups. They also assumed that the pathology staff were present and available, not only during the OSC, and that the cytopathologist could undertake other duties for 75% of the time. In addition, the grade of the laboratory staff was reduced.

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

Cost results
The total mean cost was 151.90 for a patient in the OSC group, and 120.05 for one in the DBC group. Therefore, the incremental cost per patient with OSC, compared with DBC, was 32 (95% confidence interval CI: 2 - 62).

Results from the sensitivity analysis showed that, when it was assumed that a consultant initially assessed all patients in both groups, the difference in cost was reduced to 29. Assuming that the pathology staff had to be present the whole time increased the difference to 44. Assuming that they could undertake other duties for 75% of the time reduced the difference to 27.

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

Authors' conclusions
The one-stop clinic (OSC) showed benefits for the patients in terms of anxiety scores, but only in the very short term. The costs saved by the reduction of the pre-diagnostic visits in the OSC were more than offset by those of same-day radiological and cytopathological reporting. The authors argued that the additional costs incurred by the NHS as a result of implementing the OSC policy, may not be justified in terms of the observed short-term reduction in anxiety experienced by the patients.

**CRD COMMENTARY - Selection of comparators**
The authors did not provide an explicit justification for their choice of the comparator, although DBC appears to be the current practice at the hospital involved. You should decide if this is a widely used health technology in your own setting.

**Validity of estimate of measure of effectiveness**
The analysis used a randomised controlled trial, which was appropriate for the study question. The authors reported the method of randomisation used in allocating the patients to the study groups. The use of an independent statistician helps to ensure that the randomisation process is valid. The authors did show that the patient groups were comparable in terms of their baseline characteristics, and the study sample appeared to be representative of the study population. The internal validity of the study was good.

**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**
All the categories of costs relevant to the perspective adopted appear to have been included in the analysis. Some of the resource quantities were reported separately from the costs. No statistical analyses of the quantities or costs were performed. This fact introduces uncertainty relating to the reliability of the conclusions. The price year was stated, which aids reflation exercises to other settings.

**Other issues**
The authors made appropriate comparisons of their findings with those from other studies. In addition, the issue of generalisability to other studies was addressed. Additionally, the authors appear to have reported their findings and results comprehensively. The conclusions reached appear justified within the limitations of the study.

**Implications of the study**
Compared with the DBC, the OSC shows an improvement in the anxiety levels of the patients, but only in the very short term. Therefore, the increase in cost may not be justified by the small improvement in the health outcomes. The authors acknowledge that further work is necessary in order to define more precisely the costs and benefits of different strategies to reduce delay.

**Source of funding**
None stated.

**Bibliographic details**
Other publications of related interest


Indexing Status
Subject indexing assigned by NLM

MeSH
Adult; Aged; Aged, 80 and over; Ambulatory Care /economics; Anxiety /etiology; Breast Neoplasms /diagnosis /psychology; Cost-Benefit Analysis; Costs and Cost Analysis; Female; Great Britain; Humans; Mammography /economics; Medical Staff, Hospital; Middle Aged; Outpatient Clinics, Hospital /economics; Patient Satisfaction; State Medicine /economics; Time Factors; Ultrasonography, Mammary /economics

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