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

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Abstract

Objective To determine the cost to the NHS and the impact on anxiety of a one stop clinic for assessing women with suspected breast cancer.
Study design Randomised controlled trial.
Participants Women aged 35 or over referred with a breast lump.
Study setting Teaching hospital, north west England.
Interventions Women were randomly allocated to attend a one stop clinic or a dedicated breast clinic.
Outcome measures Reduction in mean anxiety from baseline at 24 hours after the first visit and at 3 weeks and 3 months after diagnosis; mean cost per patient.
Results 670 women were randomised. Compared with women who attended the dedicated clinic, patients attending the one stop clinic were less anxious 24 hours after the visit (adjusted mean change in state anxiety −5.7 (95% confidence interval −8.4 to −3.0)) but not at 3 weeks or 3 months after diagnosis. The additional cost to the NHS of a one stop attendance was £32 per woman; this was largely explained by greater cytopathological and radiological staff costs.
Conclusion One stop clinics may not be justified in terms of a reduction in short term anxiety.

Introduction

Women with suspected breast cancer should be assessed in a dedicated clinic offering imaging and fine needle aspiration cytology at the initial visit.[1] One stop clinics that offer same day reporting of diagnostic investigations further reduce delay.[2–4] These clinics are assumed to be more cost effective because prediagnostic visits are reduced, but the consequences for other hospital services have not been quantified. One stop clinics must be provided by consultants because women are seen only once,[5] throughput will be less because more time is needed to discuss findings and management, and consultant radiologists and pathologists who usually batch report investigations must be available for the whole clinic although not always needed. Although prolonged investigations can reinforce patients' concerns,[6 7] the anxiety of women with symptomatic benign breast disease cannot always be allayed, and the additional benefit of further foreshortening the diagnostic process should be measured.[2 8]

We report a randomised controlled trial comparing the costs and benefits of a one stop policy for women with suspected cancer with those of a dedicated breast clinic.

Methods

Participants and interventions

Of 70 new appointments scheduled weekly in a dedicated clinic at Withington Hospital, Manchester, 20 were for urgent assessment of women aged 35 or over with a breast lump. Between April 1995 and November 1996, appointment clerks used a balanced block design stratified by consultant and generated by an independent statistician to randomly allocate these women an appointment in a dedicated breast clinic or a one stop clinic. Non-attenders were re-randomised. Recruitment was suspended for six months because of staff shortages. A randomised consent design was used, and women were randomised before consent was obtained. All women were sent information outlining the study. Women allocated to a one stop clinic were informed that they had been randomly selected to attend a new clinic but could opt for the usual clinic. Before assessment, a researcher discussed the trial with women in both groups; those not wishing to participate could still keep their scheduled appointment, and women allocated to a one stop clinic again had the option to change. Participants gave written consent.

Women attending a one stop clinic had a mammogram in the screening assessment unit, after which a consultant radiologist could perform ultrasonography. A consultant surgeon assessed patients when imaging reports were available. Women undergoing aspiration cytology waited while this was reviewed by the consultant pathologist. The surgeon then reassessed patients and discussed their management. Women attending a dedicated clinic were first assessed by a surgeon; if further investigations were undertaken, women were asked to return the following week to discuss the results.

We abstracted activity data from case notes at diagnosis and 12 months later and used the cancer registry to identify cases of breast cancer diagnosed elsewhere during follow up. We measured psychological distress by using the state scale of the state-trait anxiety inven-

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tory and the anxiety subscale of the hospital anxiety depression scale.[9 10] Women completed questionnaires immediately before assessment (baseline), 24 hours after the first visit (state scale), and three weeks and three months after diagnosis (anxiety subscale). The local research ethics committee approved the study.

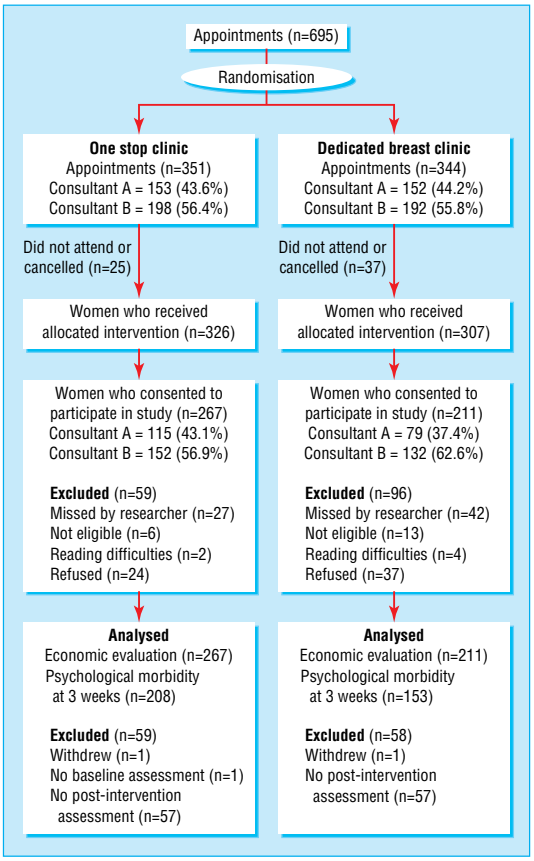
Economic evaluation

We set costs from an NHS perspective. We obtained costs of staff and investigation for the first visit and follow up visits, including 40% overheads, from South Manchester University Hospitals Trust (1998). The costs of setting up the clinic and of treatment were excluded, as were the costs of investigations that were undertaken in less than 1% of patients. We aggregated costs for each group and derived a mean cost per patient. Sixty new referrals, including 10 trial participants, were seen in the dedicated breast clinic staffed by two consultants, two senior registrars, and two registrars; each patient was allocated 18 minutes of surgical time. The remaining 10 trial participants seen in the one stop clinic were each allocated 21 minutes of consultant surgical time. We apportioned costs to reflect the grade of the surgeon undertaking the initial assessment. Nursing costs reflect the number and grade of staff rostered for each clinic. One stop clinic costs include two hours of a consultant radiologist's time because it takes 10-15 minutes to obtain and report a mammogram. A consultant pathologist and a grade 3 laboratory technician were available for the whole one stop clinic but afterwards agreed that half their time was spent on other activities while awaiting specimens, and costs were thus based on 1.75 hours of dedicated time. In the one stop clinic, initiation of investigations, transport of specimens, and retrieval of test results were expedited outwith usual services, and these costs were included in the analysis.

After initial assessment, all further visits were to a dedicated follow up clinic, irrespective of where initial assessment took place; we estimated the mean staff costs of these visits by dividing costs for each session by the average number of appointments. In the one stop clinic, the radiologist performed ultrasonography while awaiting the next set of mammograms, and we have therefore excluded operator costs. We similarly adjusted cytology costs to avoid double counting of pathology staff time.

Sample size

In a pilot study, 33% of women in a one stop clinic were anxious (score >7) three weeks after diagnosis. Assuming a control rate of 48%, 460 women were needed to detect a 15% difference between groups for 90% study power at the 5% two sided significance level. Achieving this target sample size required randomisation of 757 women, assuming that 90% would attend and that 90% of attenders would participate, with 75% of participants completing follow up questionnaires. The study period was extended because of cancelled clinics and two unexpected sources of attrition: researchers failed to identify all women before assessment, and some women were found to be ineligible. Based on our original prevalence estimates, we set a termination date to achieve 80% power. The study had 79% power to exclude a 15% difference.



Trial profile

Statistical analysis

We adopted an intention to treat approach and analysed patients in their assigned groups[11 12]; all participants contributed to the economic evaluation, but only those completing questionnaires at baseline and the time point of interest contributed to the analyses of anxiety. We used analysis of covariance to examine changes in mean anxiety score from baseline, with baseline as the covariate,[13] and Stata 6.0 to construct bootstrap 95% confidence intervals for the difference in mean cost.

Results

Six hundred and ninety five appointments were offered to 670 women, of whom 633 (94.5%) attended. We subsequently excluded 94 women—69 (10.9%) not interviewed before assessment, 19 (3.0%) found to be ineligible, and 6 (0.9%) with reading difficulties (fig). Sixty one (11.3%) of 539 remaining women declined to participate; these were more likely to have been allocated to the dedicated clinic (15% *v* 8% ($\chi^2=5.29$, df=1, P=0.021)), to have cancer (30% *v* 13% ($\chi^2=9.68$, df=1, P=0.002)), and to be older (mean age 56 *v* 49 years (t=4.91, df=537, P<0.0001)). The final study population comprised 478 women—267 (55.9%) randomised to a one stop clinic and 211 (44.1%) randomised to a dedicated breast clinic. Baseline characteristics were similar across groups (table 1).

Clinical activity

Table 2 shows results for clinical activity. Patients seen in a one stop clinic were more likely to be assessed ini-

Table 1 Baseline characteristics of 478 participating women. Values are numbers (percentages) unless stated otherwise

Baseline characteristics	One stop clinic (n=267)	Dedicated breast clinic (n=211)
Age (years):		
Mean (SD)	50 (10.5)	49 (10.5)
Range	35-86	35-95
Family history of breast cancer:		
Yes	58 (23.4)	36 (19.1)
No	190 (76.6)	152 (80.9)
Missing	19	23
Menopausal status:		
Premenopausal or perimenopausal	143 (57.4)	123 (62.1)
Postmenopausal	106 (42.6)	75 (37.9)
Missing	18	13
Presenting symptoms:		
Lump in left breast	124 (46.4)	106 (50.2)
Lump in right breast	128 (47.9)	95 (45.0)
Bilateral lump	3 (1.1)	2 (0.9)
Other	12 (4.5)	8 (3.8)
Time lapse (days) between referral and attendance:		
Median (range)	14 (0-105)	14 (0-50)
Missing	11	2
Initial assessment under care of:		
Consultant A	115 (43.1)	79 (37.4)
Consultant B	152 (56.9)	132 (62.6)
Psychological morbidity		
State-trait anxiety scale:		
Mean (SD) trait score	39.6 (10.6)	37.9 (10.0)
Missing	13	16
Mean (SD) state score	48.4 (14.0)	47.6 (14.8)
Missing	8	14
Hospital anxiety and depression scale:		
Anxiety subscale		
not anxious	110 (41.5)	88 (41.7)
anxious	155 (58.5)	123 (58.3)
mean (SD) anxiety score	9.1 (4.5)	9.1 (4.8)
missing	2	0
Depression subscale		
mean (SD) depression score	4.0 (3.5)	3.9 (3.4)
missing	2	0

tially by a consultant or a senior registrar (94.8% *v* 62.1%, difference = 32.7% (95% confidence interval 25.6% to 39.7%)), to have mammography (97.8% *v* 83.4%, 14.4% (9.2% to 20.1%)) or ultrasonography (88.4% *v* 17.5%, 70.9% (63.7% to 76.5%)) at diagnosis, and to be given a diagnosis at first visit (91.0% *v* 49.3%, 41.7% (33.9% to 49.0%)).

Anxiety

In both groups, mean anxiety scores at all time points were lower than at baseline (table 3). Reduction in mean anxiety was significantly greater for one stop clinic patients at 24 hours (difference$_{adj}$ = −5.7 (−8.4 to −3.0)) but not at three weeks (−0.2 (−1.0 to 0.5)) or three months (−0.5 (−1.3 to 0.3)). At three weeks, 41.8% (n = 87) of one stop clinic patients and 48.4% (74) of dedicated clinic patients were anxious (score >7); the equivalent figures at three months were 42.7% (94) and 47.5% (75). In both groups, baseline scores were similar in women completing and not completing follow up questionnaires.

Economic evaluation

A one stop policy cost £32 (95% confidence interval £2 to £62) more per patient; this was largely explained by the additional input of radiologists and pathologists (table 4). The exclusion of excision biopsies slightly increased the difference in mean cost (£34) but substantially reduced its variability (£27 to £41). A sensitivity analysis which assumed that a consultant initially assessed all women in both clinics reduced the difference in mean cost to £29. Assuming that pathology staff were present and not just available throughout the one stop clinic increased the difference to £44, but this fell to £27 if the cytopathologist were to undertake other duties for 75% of this time. Reducing the grade of laboratory staff had little effect.

Discussion

Compared with women attending a dedicated breast clinic, those attending a one stop clinic made fewer visits but at greater cost. Costs saved by reducing the number of prediagnostic visits were more than offset by those of same day radiological and cytopathological

Table 2 Clinical activity. Values are numbers (percentages) unless stated otherwise

	One stop clinic (n=267)	Dedicated breast clinic (n=211)	Significance
Median No (range) of days between first attendance and diagnosis	0 (0-85)	8‡ (0-190)	Z=11.67, P<0.0001
Visits before diagnosis made:			
One visit	243 (91.0)	104 (49.3)	
Two visits	19 (7.1)	78 (37.0)	Z=10.12, P<0.0001
Three or more visits	5 (1.9)	29 (13.7)	
Women who were assessed by consultant or senior registrar	253 (94.8)	131 (62.1)	χ^2=77.58, df=1, P<0.0001
Women undergoing a diagnostic procedure:			
Mammography*	261 (97.8)	176 (83.4)	χ^2=29.11, df=1, P<0.0001
Ultrasonography	236 (88.4)	37 (17.5)	χ^2=238.7, df=1, P<0.0001
Fine needle aspiration cytology†	124 (46.4)	92 (43.6)	χ^2=0.28, df=1, P=0.6
Core biopsy	12 (4.5)	9 (4.3)	χ^2=0, df=1, P=1
Aspiration of cyst	61 (22.8)	55 (26.1)	χ^2=0.5, df=1, P=0.48
Excision biopsy	14 (5.2)	9 (4.3)	χ^2=0.08, df=1, P=0.78
Women diagnosed as having:			
No abnormality detected	40 (15.0)	49 (23.2)	
Benign lump	83 (31.1)	65 (30.8)	
Cyst	81 (30.3)	55 (26.1)	χ^2=6.91, df=5, P=0.23
Other benign condition	20 (7.5)	16 (7.6)	
Ductal carcinoma in situ or atypical	4 (1.5)	1 (0.5)	
Cancer	39 (14.6)	25 (11.8)	
Mean No of visits after diagnosis	1.18	1.05	Z=0.78, P=0.44

Differences between study groups were analysed by using χ^2 test with a continuity correction for categorical data and Mann-Whitney test with normal approximation for other data.
*4 dedicated breast clinic patients had mammography repeated.
†6 one stop clinic patients and 14 dedicated breast clinic patients had aspiration cytology repeated.
‡8 days is the time from first assessment to next available follow up visit.

Table 3 Change from baseline in mean anxiety scores. Values are mean (SD) unless stated otherwise

	One stop clinic	Dedicated breast clinic	Test of significance	P value
State anxiety score:				
Baseline	48.1 (13.9)	47.2 (14.9)		
24 hours	34.5 (14.6)	39.8 (15.8)	$F_{1,389}$=17.27	P<0.0001
Hospital anxiety and depression scale anxiety score:				
Baseline	8.9 (4.4)	8.8 (4.9)		
Three weeks	7.3 (4.7)	7.4 (4.3)	$F_{1,358}$=0.35	P=0.55
Baseline	8.9 (4.4)	9.0 (5.0)		
Three months	7.0 (4.6)	7.5 (4.7)	$F_{1,375}$=1.51	P=0.22

State anxiety scores: n=392 (220 in one stop clinic and 172 in dedicated breast clinic).
Hospital anxiety and depression scale anxiety scores at baseline and three weeks: n=361 (208 in one stop clinic and 153 in dedicated breast clinic).
Hospital anxiety and depression scale anxiety scores at baseline and three months: n=378 (220 in one stop clinic and 158 in dedicated breast clinic).

Table 4 Mean cost (£) to the NHS of assessment and 12 month follow up of a woman referred for investigation of a breast lump

	One stop clinic	Dedicated breast clinic
Staff costs		
Assessment:		
First clinic visit		
surgical	14.63	9.84
pathological	12.34	N/A
radiological	9.90	N/A
nursing	5.83	2.96
administrative and porterage	7.38	2.92
Other assessment clinic visits	0.73	4.39
Post-diagnosis clinic visits	7.94	7.02
Costs of investigations		
Investigations undertaken during assessment:		
Mammography	37.09	32.36
Ultrasonography	5.03*	3.33
Fine needle aspiration cytology	10.42*	16.34
Core biopsy	2.21	2.10
Excision biopsy	31.33	33.34
Investigations undertaken during 12 month follow up	7.07	5.44
Total mean cost	151.90	120.05

The cost of a mammogram was £37.94, an ultrasound scan £18.97, aspiration cytology £32.52, a core biopsy (including equipment) £49.25, and day case and inpatient excision biopsies (including pathology costs) £539 and £812.
N/A = not applicable.
*In the one stop clinic, costs of an ultrasound scan and aspiration cytology were adjusted (see text).

reporting. The psychological benefits of attending a one stop clinic were seen only in the short term.

Methodological considerations

The optimum way of delivering a one stop service has not been defined.[2–4] Our clinic followed a breast screening model—women with a high index of suspicion of cancer had mammography before clinical assessment. This strategy, used in other one stop clinics,[4] may allow for more efficient use of radiologist's time but results in a higher uptake of investigations than in a dedicated breast clinic where referral for investigation follows clinical examination. In the dedicated clinic, ultrasonography was usually requested by the surgeon when mammographic and cytopathological investigations were equivocal. In the one stop clinic, however, the decision to perform ultrasonography was made by the radiologist after reviewing the mammogram, a common practice when assessing women with abnormal screening mammograms. Thus the imbalance in uptake of ultrasonography (which contributed little to the difference in costs) follows from the translation of an investigational strategy from one area of clinical activity to another.[14] Costs might have been less if the service had been organised differently, but this is untested. Data collected from 58 patients showed little difference between groups in patient costs. Patient preferences could not be reliably defined as women had experienced only one type of clinic.[15]

We used a modified Zelen design—consent was sought from patients after randomisation, and only those agreeing to participate were analysed.[16] This design was imposed by the need to minimise delay between referral and first appointment and to schedule appointments for busy clinics. To wait to learn whether a woman wished to participate before scheduling her appointment would have resulted in unacceptable delay. To postpone randomisation until clinic attendance, the preferred option, was impossible because the one stop clinic had to start before the dedicated clinic to allow for processing and reporting of investigations and their possible repetition. We did not need to consider the impact of patient transfer on the observed treatment effect because no one switched clinics.[16] Some women did not attend, and others could not be identified before assessment; this was more common in the dedicated clinic held in the busy main outpatients department.

Comparison with other studies

Although a similar unsustained reduction in psychological morbidity in women attending a one stop clinic has been reported elsewhere, costs were not measured.[2] Concerns have been expressed that same day reporting might compromise diagnostic accuracy. Harcourt et al report two "missed" cancers in one stop clinic patients and one missed cancer in two stop clinic patients,[2] and Eltahir et al report four missed cancers during a three year follow up of 1110 one stop referrals.[4] Our study was not powered to detect differences in this outcome; the only "missed" cancer occurred in a one stop clinic attender.

Implications for the NHS

Attention is increasingly focused on delays in the patient's cancer journey.[17] Same day reporting benefits only those women who otherwise would not have been given a diagnosis at their first visit to a dedicated breast clinic; in this trial nearly 50% of women attending a dedicated clinic were given a diagnosis at this visit. We consider that the additional cost to the NHS of this one stop clinic may not be justified in terms of the observed short term reduction in anxiety. Further work is needed to define more precisely the costs and benefits of different strategies to reduce delay. These should be compared with the benefits of further investment in interventions of proved effectiveness.

What is already known on this topic

One stop clinics have been set up for a wide range of conditions

Rapid alleviation of anxiety has been observed in women attending a one stop clinic for assessing breast problems

The additional costs of providing this service have not been adequately quantified

What this study adds

The benefits of one stop clinics are, in the main, short term

The costs saved by the reduction in the frequency of outpatient visits are more than offset by those associated with same day reporting of diagnostic tests

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and VL. PH advised on the measures of psychological morbidity. NB, FK, CB, and PH contributed to interpreting the findings. MJ advised on the economic evaluation and collected and interpreted cost data. PD is guarantor for this study.

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Competing interests: None declared.

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Commentary: one stop clinics should not be abandoned

J Michael Dixon

Before the one stop breast clinics that already exist are dismantled on the basis of the results of this important study, several issues need to be considered. Could the way the study was organised have influenced the results? What are patients' views of one stop breast clinics? Is it feasible for all patients to be offered a one stop diagnostic service?

Although the one stop clinics as organised during the Manchester study did not seem to be cost effective, there are reasons for this. More patients seen in the one stop clinic had mammography (97.8% *v* 62.1%) and ultrasonography (88.4% *v* 17.5%). The explanations for this are twofold. Firstly, more patients in the one stop clinic were seen by a senior doctor, who organised more mammograms. Secondly, the radiologist in these clinics performed ultrasonography without discussion with the surgeon to determine whether it was indicated clinically. We do not know whether this policy increased diagnostic accuracy: ultrasonography is a sensitive test for the detection of breast cancer and should reduce the number of patients who have a delay in diagnosis.[1] A more selective use of ultrasonography would have allowed more patients to be seen in each one stop clinic, which would have used pathology staff more efficiently and should reduce costs per patient of a one stop diagnostic service. No details of administration costs are given, but these should be less with a one stop clinic; the number of letters per new patient episode decreased dramatically from a mean of 4.3 to 1.5 with the introduction of a one stop clinic in Edinburgh.

One stop clinics significantly reduce short term anxiety but not surprisingly do not have long term effects. Anecdotally, doctors attending our clinic as patients report that a one stop service minimises distress not only for them but for their partner and family (not considered in Dey and colleagues' paper) and limits the disruption to their own and their patients' lives. A significant improvement in patients' rating of their experience attending diagnostic breast clinics followed the introduction of a one stop clinic in Edinburgh.[2] Waiting for results was the major complaint before the introduction of a one stop service and problems with car parking the major problem afterwards.

Cytology is the only available method of obtaining an immediate definitive diagnosis, and this needs an experienced cytopathologist (currently in short supply in the United Kingdom). Core biopsy alone or combined with cytology is increasingly used as this is easier to interpret.[3] Those centres that use core biopsy alone cannot currently offer a one stop diagnostic service.

One stop breast clinics are not possible in every centre and are unlikely to be cost effective in centres seeing small numbers of patients per clinic. They should not yet be abandoned, however, but their proponents do need to show that if they see more patients per clinic than the Manchester group, and use a more selective policy for ultrasonography, the benefits are not outweighed by extra costs.

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