FEASIBILITY OF DAY SURGERY FOR BREAST CANCER IN GLASGOW

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Summary of Thesis

Over the years, the surgical management of breast cancer has become less invasive due to various factors. Breast conserving surgery and lesser axillary surgery are performed whenever possible. Early stage at diagnosis made possible by breast screening and earlier presentation of symptomatic cancers due to increased awareness has meant that more patients are undergoing breast conserving surgery. Sentinel node biopsy and axillary sampling have helped reduce arm morbidity. These changes have made breast cancer surgery more amenable to day surgery. At the same time, the benefits of early discharge and day surgery have been increasingly recognised in all surgical specialities. In 2007, when this research was undertaken, majority of breast cancer patients in Glasgow underwent operations as inpatients.

The aims of this thesis were to establish the evidence base for day surgery in breast cancer and analyse the feasibility, acceptability and safety of performing day surgery in breast cancer patients in Glasgow.

In Chapter 2, a systematic review of literature for studies comparing day surgery with inpatient surgery in breast cancer is presented. This was undertaken to establish the present evidence. A randomised controlled trial is the gold standard when comparing one intervention with another. However, this systematic review revealed lack of any randomised controlled trials in literature comparing day surgery with inpatient surgery for breast cancer. Only observational studies were found and these showed day surgery for breast cancer to be safe with high patient satisfaction.

In Chapter 3, the feasibility of day surgery for breast cancer in Glasgow was examined. The postoperative length of hospital stay of patients undergoing surgery for breast cancer was studied across five centres in Glasgow. It was noted that 50 percent of patients were discharged within a day of their operation. An analysis of socio-demographic and clinico-pathologic factors influencing postoperative length of stay for all

breast cancer surgical patients revealed that the most important factor influencing postoperative stay was the axillary procedure performed. It was seen that symptomatic cancer patients undergo more extensive surgery and are more likely to stay longer in hospital. Patients undergoing re-operations contributed 20 percent to the hospital bed utilisation. Fifty percent of the patients who were discharged within a day of their operation, were potentially thought to be suitable for day surgery.

In Chapter 4, the acceptability and safety of day surgery for breast cancer, evaluated in a pilot randomised controlled trial is presented. In this trial, day surgery was compared with inpatient surgery for patients undergoing breast conserving surgery with axillary sampling or sentinel node biopsy. Physical and psychosocial outcomes were examined using validated questionnaires. In a patient satisfaction survey, day surgery was found to be highly acceptable to patients. No difference was found in the physical outcomes between the two groups. Day surgery patients were noted to have a significantly better quality of life one week after their operation. Therefore, this trial found day surgery to be a safe option.

In conclusion, the results of the present thesis show that day surgery for breast cancer is a feasible option that was rated by the patients as highly acceptable and had better quality of life outcomes. Moreover, equivalent physical outcomes were noted in both the groups.

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Dedication

I would like to dedicate this thesis to Prof. Timothy G. Cooke (Head of Academic Unit of Surgery, Glasgow Royal Infirmary), who not only was my supervisor but also a guiding light. His sad demise in 2008 was a huge personal and professional loss.

Author's Declaration

I declare that the work presented in this thesis has been solely carried out by me, except where indicated below:

The search strategy for the systematic review was formulated with the help of Dr. Helen S. Marlborough, Senior Assistant Librarian, Biomedical & Life Sciences Faculty Support at the University of Glasgow.

Dr. Sheila Stallard carried out independent review of literature and read abstracts in parallel for the systematic review conducted in this thesis. This is in keeping with the advice that such searches should be conducted independently by two authors.

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Publications and Presentations

The work carried out in this thesis has so far led to the following publications and presentations:

Publication

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8th International Association of Ambulatory Surgery Meeting, Brisbane, Australia, July 2009

Study design of pilot randomised clinical trial comparing day surgery and inpatient surgery for breast cancer. S Marla, S Stallard
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Poster Presentations

Breast Cancer Surgery: Factors influencing postoperative hospital stay in West of Scotland
S Marla, D C McMillan, P G Horgan, S Stallard
8th International Association of Ambulatory Surgery Meeting, Brisbane, Australia, July 2009

Factors influencing postoperative hospital stay after Breast Cancer surgery.
S Marla, S Stallard
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S Marla, L Romics, K Ogston, TG Cooke, S Stallard
31st Annual San Antonio Breast Cancer Symposium, San Antonio, Texas, USA December 2008

How many breast cancer patients would be potentially suitable for ambulatory surgery in South Glasgow?
S Marla, S Stallard
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Abbreviations

BADS	**British Association of Day Surgery**
BCS	**Breast Conserving Surgery**
BMI	**Body Mass Index**
DCIS	**Ductal Carcinoma in situ**
Depcat	**Deprivation Category**
EWB	**Emotional Well Being**
FACT B	**Functional Assessment of Cancer Therapy Breast**
FACT G	**Functional Assessment of Cancer Therapy General**
FWB	**Functional Well Being**
LOS	**Length of stay**
MOOSE	**Meta-analysis of Observational Studies in Epidemiology**
NHS	**National Health Service**
NICE	**National Institute of Health and Clinical Excellence**
OR	**Odds ratio**
PASWEB	**Patient Administration System**
PONV	**Postoperative nausea and vomiting**
PWB	**Physical Well Being**
SNB	**Sentinel Node Biopsy**
SSI	**Surgical Site Infection**
SWB	**Social Well Being**
UK	**United Kingdom**
USA	**United States of America**

1.0 Introduction

Until recently, breast cancer patients in Glasgow in common with women in the whole of the United Kingdom (UK) have had their surgical treatments in hospital as inpatients. In Glasgow, women have been treated in a variety of inpatient settings. In one hospital in the city, there is a separate breast ward with its own trained nurses. In the other hospitals, patients are either in a surgical ward with general nursing staff or in dedicated areas within surgical wards, with specially trained and committed nurses. In the recent past (up to five years ago) when all women having breast surgery in Glasgow had axillary clearance, they would stay in hospital 3, 4 or 5 days post-operatively until their drains had settled and could be removed. Very few were offered the opportunity to go home with their drains in situ. These few days in hospital meant that women had time with experienced ward nurses who provided them with information and support. They had regular physiotherapy and exercises. Being in hospital meant that they met their surgeon and breast care nurse daily and patients and staff got to know each other well. It also meant patients had contact with other women undergoing similar procedures. Some patient groups who met in hospital carried on meeting and providing support to each other long after their discharge from hospital, remaining friends for years in some cases. The disadvantage of this period of time in hospital was that women were separated from their own sources of support at a crucial time. They were separated from their families and especially for younger women their children at a time when they were vulnerable. They saw themselves as ‘patients’ in a sick role for those days, resting and not returning to their normal lives quickly after surgery. For older patients they were in danger of becoming more dependent and institutionalised, even within a few days, potentially delaying their recovery and return to functioning.

1.1 Recent changes in breast surgical practise

Several significant changes have taken place that have gradually altered both the practise of breast surgery in Glasgow as well as in the UK as a whole.

The first change was the introduction of the NHS Breast Screening Programme (in Glasgow from 1990 onwards) with a gradual implementation across the city and the West of Scotland. Secondly, over the past 5 years there has been a change in axillary surgery and away from axillary clearance for all patients. A gradual shift has occurred towards the smaller procedures of axillary node sampling, blue-dye assisted node sampling and now sentinel node biopsy (SNB) with radioisotope and blue dye.

Partly as a result of earlier detection through screening and partly as result of increased awareness and earlier presentation of symptomatic patients, the third change had been towards more breast conserving surgery (BCS). Although there are always going to be patients who need mastectomy, breast conservation rates have increased. These three factors have been considered separately below.

1.1.1 The Impact of the breast screening programme

The NHS Breast Screening Programme was initiated as a result of the 'Forrest Report', published in 1986.[1] Regular mammography had proven effectiveness in reducing breast cancer mortality in women aged over 50 years.[1] Initially the programme offered 3-yearly mammography to women between the ages of 50 and 64 years. In 2000, on the basis of the evidence gained through pilot studies, the NHS Cancer Plan was implemented increasing the upper limit from 64 to 70 years.[2] In 2007, the Cancer Reform Strategy announced further expansion of the NHS Breast Screening Programme to increase the service to nine screening rounds between 47 and 73 years with a guarantee that women will have their screening before the age of 50 years.[3]

In 2006, 29% of breast cancers in UK were diagnosed in women over the age of 70, 52% were diagnosed in women between 50 and 70 years of age and 19% in women less

than 50. In the 50 to 70 year age group, 52% of cancers were screen detected. Breast screening has also lead to an increase in the number of non-invasive tumours.

Screen-detected cancers in general have been found to have better prognosis. They have been noted to have a relatively smaller size, with 78% being 20mm in diameter or smaller compared to 48% of the symptomatic cancers.[4] Similarly, 28% of screen detected cancers were noted to be Grade-1 compared to 12% of symptomatic cancers and 23% had node positive disease compared to 51% of the symptomatic cancers.

This meant that many screen detected cancers particularly non-palpable cancers could be treated by breast conserving surgery rather than mastectomy. As fewer patients overall were now node positive, it seemed unjustifiable to continue to carry out axillary clearance on everyone, disadvantaging the majority who were node negative. Women with small screen detected cancers were ideal candidates for axillary sampling or SNB and these procedures could easily be carried out without the need for an axillary drain.

1.1.2 Introduction of node sampling and sentinel node biopsy

The main disadvantage of axillary clearance is the potential morbidity such as lymphedema, pain, stiffness and shoulder weakness.[5] Although random four-node sampling was shown to be an accurate way to separate node positive from node negative patients in the Edinburgh studies in the 1990's, it is also associated with morbidity particularly for node positive patients who need axillary radiotherapy or completion axillary clearance.

The first Edinburgh trial compared axillary sampling with mastectomy and radical mastectomy in a randomised study.[6] A sample of four nodes was removed from the axillary fat which was in relation to the axillary tail of the breast. Patients who had a positive axillary sample were given radical radiotherapy. There was no significant difference between overall survival and locoregional recurrence between the two groups after 10 years. This was followed by a further randomised trial comparing axillary

sampling with axillary clearance in breast conserving surgery.[7] The locoregional recurrence and five-year survival in both groups was similar. However, sampling patients had more arm related morbidity due to axillary radiotherapy. Blue-dye directed four node axillary sampling is now performed in the same centre with false negative rates reported at 2.4%.[8]

The attraction of SNB is that it is a minimally invasive way to stage the axilla. The term 'Sentinel Lymph Node' was first used by Cabanas in the management of penile cancers in 1977.[9] The Sentinel Lymph Node hypothesis states that tumour cells from a primary carcinoma migrate through lymphatic channels to a single lymph node before involving further lymph nodes within that basin. The intraoperative identification of the sentinel lymph node in patients with breast carcinoma was shown to be successful by Krag et al. using 99m-Technetium-labeled sulfur, Giuliano et al. using blue dye, and by Albertini et al. using a combination of 99m-Technetium-labeled sulfur colloid and blue dye, with initial identification rates reported of 82%, 66%, and 92%, respectively.[10-12] One of the earliest studies of sentinel node biopsy in breast was carried out in Glasgow by Professor Cooke in 1997.[13] The ALMANAC trial in UK has since shown that SNB is associated with reduced arm morbidity and better quality of life than standard axillary treatment and reported high identification rates and low false negative rates.[14,15] The international acceptance of the SNB over routine axillary clearance is based on the fact that it is associated with a lower risk of the common morbidities noted with axillary clearance. The SNB also allows the pathologist to study the few sentinel lymph nodes removed in greater detail for tumour burden compared with the examination of a large number of lymph nodes removed by clearance. The 2009 NICE guidelines states that SNB should be the treatment of choice for early operable breast cancer with normal axillary ultrasound scanning.[16]

These changes therefore to less invasive axillary surgery meant that not all breast cancer patients have needed to stay in hospital for the same length of time as they did when they all had axillary clearance with drains.

1.1.3 Evolution of breast surgery

Breast conserving surgery was first performed in the late 1970's. Until then all breast cancer patients had mastectomy. The trials in America and Milan in the late 1970's and 1980's established that breast conserving surgery with radiotherapy is as safe as mastectomy both in terms of local recurrence and survival from breast cancer.

Trials conducted in the 1970-1980 period compared mastectomy with segmentectomy with or without radiotherapy. Veronesi in Milan randomised patients with tumours less than 2 cm with no palpable axillary lymph nodes to Halsted radical mastectomy vs. quadrantectomy with axillary node dissection and radiotherapy. There was no difference in disease-free or overall survival, or locoregional recurrence between breast conservation with radiotherapy and radical mastectomy.[17] This was the first study to demonstrate that excision of the tumour followed by radiotherapy gave equivalent results to mastectomy. The NSAPB B-06 trial was initiated in 1976 and evaluated breast conservation in Stage I/II breast cancer. Fisher and colleagues randomized 1843 patients with cancers less than 4 cm into 3 arms: total mastectomy, segmental mastectomy, and segmental mastectomy with radiation. All patients received axillary node dissection, and those with positive nodes received adjuvant chemotherapy. The results of this study at 5 and 8 years showed no difference in disease-free survival among the 3 groups.[18,19] This was the first trial to compare mastectomy with wide local excision with or without radiotherapy. An increase in local recurrence was noted in the segmentectomy group without radiation. This supported the use of radiotherapy to reduce local recurrence. The National Institute of Health Consensus Conference in 1990 recommended breast conserving surgery for patients with Stage I and II breast cancer.[20] The randomised trials

which formed the basis of this statement have since reported long-term results (10 to 18 years follow-up) and have shown no significant difference in mortality due to breast cancer, although the rate of locoregional recurrence has been found to be higher after breast conserving surgery.[21,22]

In the last two decades, there has been a progressive increase the proportion of women undergoing breast conserving surgery. In Glasgow, at the start of this study, over 65 percent of women were undergoing BCS.[23]

1.2 Recent changes in general surgical practise

As well as the changes taking place in breast surgery that have been described, there have also been significant changes in the philosophy of perioperative care in general surgery. Increasing evidence has shown that preoperative assessment, optimisation of patients for surgery and early mobilisation is of great benefit to patients. The idea of 'fast track surgery' and rapid return to tasks of daily living reduces morbidity and mortality after all types of surgery. The Whitehall II study showed that the risk of death after any type of surgery was two-fold higher in patients who had had seven or more days off work compared with less than seven days off work.[24]

The concept of fast-track surgery was introduced in the early 1990s.[25] The idea encompasses preoperative medications, perioperative fluid management, metabolic and thermoregulation, fast track anaesthetic and surgical techniques and management of postoperative pain and nausea and vomiting. These techniques have been used both for patients undergoing day surgery and for inpatients undergoing more complex surgeries such colorectal surgery or cardiac surgery. In these patients, fast track surgery helps in early discharge from hospital.[26]

For general anaesthetic cases the pharmacokinetics of the newer generation of drugs used in anaesthesia (sedatives, anaesthetic agents, analgesics and muscle relaxants) enable rapid onset of anaesthesia with a short duration of action and predictable effects without accumulation and with minimal side effects. Rapid and short-acting drugs and the increasing use of intravenous anaesthetic techniques facilitate the early recovery process. Prophylactic use of non-opioid analgesics and antiemetic drugs reduce postoperative side effects and enhance recovery while reducing hospital stay.[27]

Studies have evaluated this approach in colonic surgery in randomised controlled trials.[28,29] In one study, the intervention groups received intravenous fluid restriction, unrestricted oral intake with prokinetic agents, early ambulation, and fixed regimen

epidural analgesia.[29] They found a significant decrease in the length of stay in the intervention group compared to the control group (5 days vs. 7 days) without any concomitant increase in complications. Similar experiences have been found in other surgical specialties such as cardiac surgery where early tracheal extubation has been found to be beneficial and in urology procedures where length of hospital stay has been significantly reduced after minimally invasive procedures.[30,31] This approach requires a cooperating team of motivated nurses, anaesthetists, and surgeons. Moreover, patient education and information about the procedures and the expected time course are important. An essential part of the concept is that the active role of the patient is to be emphasized.

1.3 Changing role of day surgery in general surgery

The use of day surgery has been increasing gradually over the past 20 years and more rapidly over the past few years. It was first used in children where it was noted in 1909 by James Nicoll a Glasgow paediatric Surgeon that 'bed rest was impractical in children' anyway. Also, that 'it was detrimental to children to be separated from their mothers and be kept in hospital when they could go home'.[32]

There was a rapid rise in day surgery in the United States of America (USA) where it was mainly seen as a way to better utilise resources. It was seen as being a possible alternative to hospitalisation without harm coming to the patient provided good selection criteria were employed.[33]

In UK, after the work done by James Nicoll, it was only in the 1950s before surgeons questioned the wisdom of enforced bed rest following surgery and considered the dangers this exposed the patient to.[34] Surgeons were starting to discuss the possibility of treating more patients through the same number of beds (due to reduction in lengths of stay) and the potential for day surgery to reduce waiting lists.[34,35] The gradual move to day surgery in the UK was largely driven by a few enthusiasts throughout the 1970s and 1980s until a report entitled 'Guidelines for day case surgery' was produced in 1985 (revised in 1992) by the Royal College of Surgeons of England.[36] This report stated that 'day surgery is now considered the best option for 50 percent of all patients undergoing elective procedures' and was published at a time when the national average was under 15%. British Association of Day Surgery (BADS) was founded in 1989 to promote day surgery with an emphasis on safety, quality and excellence.

1.4 Definitions of day surgery

Definitions of day surgery vary widely. In the UK, day surgery is defined as the admission of selected patients to hospital for a planned surgical procedure with them being allowed to return home the same day.[37] However, when comparing day surgery rates for a particular operation, it is important to realise that different definitions are used around the world and some countries (e.g., North America) include patients with a stay of less than 24 hours.

Internationally agreed terminology, abbreviations and definitions as proposed by the International Association for Ambulatory Surgery are shown in Table 1.1.[38]

1.5 Global Day Surgery

Day surgery is fast becoming common for nearly all elective surgery. In countries such as the USA and Canada, it accounts for nearly 90% of all surgery performed, but remains much less common in many other countries.[38] A survey conducted by the International Association for Ambulatory Surgery in 2003, which used a basket of 35 procedures, found a global increase in day surgery activity but noted wide variation. (Table 1.2) USA and Canada followed closely by the Scandinavian countries had the highest rates of day surgery.[39] The survey also showed variation within countries between various specialties and between the procedures being performed. Reasons quoted for this variation included limitations of data completeness, financial reimbursement of day cases, regulations and incentives in different countries and individual practices of surgeons and anaesthetists.

1.6 Current Practice in the United Kingdom

The NHS Plan 2000 in England set a target of performing 75% of elective operations as day surgery. The Audit Commission in England in 2001 set forward a basket of 25 procedures for the NHS Trusts which are used as performance indicators.[40] (Table 1.3) The Planned Care Improvement Programme in Scotland supports the idea of a basket of procedures and supports the NHS Trusts to achieve their target.[41]

1.6.1 The British Association of Day Surgery

BADS published a Directory of Procedures in 2006 covering 160 procedures across nine surgical sub-specialities which set targets for surgical teams.[42] Each operation was divided into four possible treatment options, ranging from management in a treatment room to requiring a 72-hour stay in hospital. (Table 1.4)

While the basket of procedures is a tool for assessing day surgery performance across NHS Trusts, the BADS directory has extended its remit and now promotes quality care in both day case and the short stay surgery setting. Within the list of BADS procedures breast biopsy is included (but not defined as benign biopsy or wide local excision for cancer) and recently sentinel node biopsy has been added.[42]

The trends across UK over the last decade have shown an increase in day surgery, however, there has been a great variability across NHS Trusts both in England and Scotland.[43,44] The Scottish report noted the main barriers to increasing the use of day surgery to be inappropriate and inadequate use of day surgery units, poor management and organisation of day surgery units, and a preference among some clinicians for inpatient surgery.[44]

1.7 Selection criteria for Day Surgery

Selection of patients for day surgery involves a combination of criteria.

1.7.1 Age

Both medical and social problems tend to increase with age, but these are considered independently, without any arbitrary upper age limit.[45] There is an association between increasing age and the development of significant changes in intra-operative haemodynamics with more intraoperative cardiovascular events (OR =1.4) noted in a study.[46] The study found significantly lower postoperative events (OR = 0.4), postoperative pain (OR = 0.2) and nausea and vomiting (OR = 0.3). Elderly patients also benefit from day surgery through a significant reduction in postoperative cognitive dysfunction.[47] This Scandinavian study suggested that elderly patients were less likely to have cognitive dysfunction if they were treated as out-patients for minor surgical procedures (OR = 2.4).

1.7.2 Obesity

Current British guidelines suggest patients with a body mass index (BMI) less than or equal to 35 $kg\,m^{-2}$ should be acceptable for day surgery, providing there are no other contraindications, while those of BMI 35–40 $kg\,m^{-2}$ should be acceptable for most procedures.[48] Currently, 91 percent of Canadian anaesthetists would accept patients of BMI 35–44 $kg\,m^{-2}$ for day surgery and half would accept patients over 45 $kg\,m^{-2}$, provided they were otherwise healthy.[49] BMI, however, cannot be looked in isolation and association of a high BMI with other lifestyle risk factors like smoking and poor overall fitness would increase the risks associated. Hypertension, congestive cardiac failure and sleep apnoea are also all common in morbid obesity and dramatically reduce the acceptability of these patients for day surgery.[49]

1.8 Why is Day Surgery increasingly being promoted?

There has always been the argument in favour of day surgery from the patient centred point of view and the acknowledgment that hospitalisation might not be good for a person. Physically, as has been described, early mobilisation is good, and psychologically patients may perceive their procedure as less serious and therefore be less anxious about it by being a day case.

In the background, however, is the argument about the use of NHS resources. Whereas it is imperative that we should be aware of the cost of patient care and be trying to use resources wisely, there is resistance to day surgery from clinicians. This feeling of unease centres around the idea that we are hurrying patients out of hospital instead of allowing them time to recover; that we are perhaps putting the cost of treatment above the quality of care. There is a feeling that day surgery is adequate and safe but perhaps not optimal for patients. There is worry that the patient centred argument is an excuse for the cost argument. Would this be particularly the case for patients with breast cancer?

1.8.1 Evidence from day surgery trials

What is the evidence therefore from trials of day surgery vs. standard inpatient care, in terms of physical and psychological outcomes?

Most of the studies in literature have been carried in laparoscopic cholecystectomy. In a meta-analysis of randomised trials, day-case laparoscopic cholecystectomy was reported to be a safe and effective way of treating gall stone disease.[50] While there have been many clinical trials comparing laparoscopic cholecystectomy done as inpatient and as day case, there are very few randomised trials comparing other surgeries.[51] Most studies for general surgical procedures have been feasibility studies.[52,53] Laparoscopic Nissen's fundoplication, varicose veins surgery and laparoscopic inguinal hernia repair have all been reported to be feasible in the day case setting with low readmission rates.[52-54] There are randomised controlled trials comparing various outcomes for cataract surgery

performed as day surgery or inpatient surgery.[55,56] These have reported no significant difference in outcomes.

1.8.2 Mortality and morbidity of day surgery

The incidence of death and major morbidity directly associated with day surgery is extremely low. Warner and colleagues followed 38,598 ambulatory surgical procedures for 30 days after surgery. They documented only four deaths, two of which were caused by myocardial infarction, and two were the result of automobile accidents.[57] In the same study, 31 patients (0.08%) had major morbidity including myocardial infarction, central nervous system deficit, pulmonary embolism, and respiratory failure. In their recent work, Jenkins and Baker demonstrated similar low mortality rate, 0.5 per 10 000 anaesthetics.[58] Unplanned return visits to hospital and re-admissions within 30 days directly related to day-surgery procedures range from 0.28% to 1.5%.[59,60] In one study there was a steady reduction in unplanned postoperative admissions as experience with appropriate clinical pathways increased.[61]

1.8.3 Mortality and Morbidity of breast surgery

The mortality rate after breast surgery is very low. El-Tamer and colleagues showed that out of 1660 patients who underwent a mastectomy, four (0.24%) died, but none of the 1447 patients who underwent breast conserving surgery with axillary surgery died.[62]

Overall, breast surgery carries a low morbidity rate.[62] Patients undergoing mastectomy are more likely to develop complications compared with breast conserving surgery.[62] The most common morbidity found in the above study was wound complications with an overall wound infection rate of 3 percent. Gupta and colleagues, in a randomised trial found the overall wound infection rate after breast cancer surgery to be about 18 percent with no difference in the infection rates with antibiotic prophylaxis.[63] Rotstein and colleagues found that wound infection after breast cancer surgery varied

between 3 percent for lumpectomies to19 percent for mastectomies.[64] In addition to the type of procedure, factors significantly associated with the development of clean surgical wound infection included: presence of surgical drains, prolonged preoperative stay, length of surgery and greater mean age. Early complications (within 30 days of surgery) such as seroma formation, wound infection and parasthesias have been reported to be significantly more common in patients undergoing axillary lymph node dissection compared to sentinel lymph node biopsy.[65]

1.8.4 Patient Satisfaction

A number of studies have reported high levels of patient satisfaction with day surgery.[66-68] Patient satisfaction can be optimized by achieving or avoiding certain circumstances, such as good postoperative pain control,[69] short waiting time before surgery, courtesy of staff and friendly environment; avoidance of patients feeling that they are being discharged too early or rushed; follow-up by telephone on the following day.[70]

1.8.5 Economic Outcomes

The financial benefits of day surgery over inpatient surgery are well established, with hospital costs ranging from 10% to 68% lower for day surgery than for the same procedures on an inpatient basis.[71,72]

The economic benefits of day surgery include shorter hospital stay, which enables a higher number of patients to be treated, thereby reducing waiting lists. This helps in release of inpatient facilities for more complex and emergency cases. There is also reduction in disruption of patients' daily routines, with lower levels of absence from work or problems providing care for others.[70]

1.9 Possibilities of day surgery for breast cancer

Given that most women with breast cancer feel well, and their surgery is not always extensive they would potentially be a group to whom day surgery could be offered. Women having BCS with or without localisation and SNB would be an ideal group. In thinking about day surgery for breast cancer, however, it is difficult to separate the technical aspects of the operation itself from the 'whole package' of ward care surrounding the surgery, as described above. If a woman having day surgery for her breast cancer is to receive this same standard of care as she would get in the ward she may have to have multiple trips to the hospital to meet with various team members and this in itself may give added burden to the woman and her family. Organising trips for breast care nurse meetings, physiotherapy etc. may be more difficult than having a few days in a ward. Without the ward contact with other patients she may feel isolated.

These are some of the issues I have tried to address in this thesis. I have searched the literature to find out what has been studied with regard to breast cancer surgery in a day setting. I will discuss the various outcomes of day surgery for breast cancer and identify the deficiencies in present world literature with regards to this. Although day surgery is being promoted in the NHS,[40] I have tried to work how many of our breast cancer patients in Glasgow may actually be suitable for day surgery in real life. I have described current practise and studied the length of stay in hospital for our patients now, in order to find out how this would change if we were to start to offer day surgery. I have analysed this across the city of Glasgow, looking at the postoperative length of stay (LOS) of all breast cancer patients. The patients' sociodemographic characteristics, comorbidities, their mode of presentation, stage of disease, the type of operations they underwent and the influence of these factors on the postoperative LOS have been examined. I then hypothesised that day surgery was equivalent to inpatient surgery for patients undergoing breast cancer surgery. In order to examine this, a pilot randomised controlled trial comparing day surgery with

inpatient surgery for breast cancer looking at both physical and psychological outcomes was carried out. From this trial I have tried to define key elements of day surgery care that should be audited if we are to assess the quality of day surgery for breast cancer in the future.

Table 1.1 Internationally agreed terminology, abbreviations and definitions as proposed by the International Association for Ambulatory Surgery[38]

Terminology	Synonyms and definitions
Day surgery (DS)	Ambulatory surgery (AS), same-day surgery, day only
Day surgery centre (DSC)	Ambulatory surgery centre (ASC), day-surgery unit (DSU), ambulatory surgery unit, day clinic
	A centre or facility designed for the optimum management of an ambulatory surgery patient
Extended recovery	23 hours, overnight stay, single night
	Treatments requiring an overnight stay before discharge
Short stay	Treatments requiring 24–72 hours in hospital before discharge
Outpatient	A patient treated at a hospital who is not admitted for a stay of 24 hours or more
Inpatient	A patient admitted into a hospital, public or private, for a stay of 24 hours or more
Office-based surgery/office procedure	An operation or procedure carried out in a medical practitioner's professional premises, which provide an appropriately-designed, equipped service room(s) for its safe performance
Day surgery procedure, ambulatory surgery procedure	An operation or procedure which is not outpatient- or office-based, where the patient is discharged on the same working day

Table 1.2 Selected results from International Association for Ambulatory Surgery survey 2003[39]

	Percentage of total surgery	Percentage of basket	Hernia (%)	Lap. Chol. (%)	Breast excision (%)	Mastectomy (%)
Australia 2003	41	74	23	2	65	9
Belgium 2004	30	-	20	1	58	3
Canada 2002	87	84	71	44	93	9
Denmark 2004	55	79	73	19	45	7
England 2003	-	63	42	3	-	2
Finland 2003	37	62	46	10	17	-
France 2003	-	45	8	0	24	7
Germany 2003	37	61	6	1	35	9
Hong Kong 2003	-	43	25	5	58	<1
Italy 2002	29	41	30	2	64	2
Netherlands 2002	50	70	38	2	41	<1
Norway 2003	48	68	63	12	46	12
Poland 2003	2	-	-	-	-	-
Portugal 2003	11	19	15	1	29	1
Scotland 2003	39	66	6	1	43	2
Spain 2003	28 - 44	54	6 -52	0 -10	-	-
Sweden 2002	50	67	69	11	41	6
USA 2003	-	84	84	50	98	57

Table 1.3 The Audit Commission of England's Basket of 25 Procedures[40]

S.No.	Procedure
1.	Orchidopexy
2.	Circumcision
3.	Inguinal hernia
4.	Excision of breast lump
5.	Anal fissure dilation/excision
6.	Haemorrhoidectomy
7.	Laparoscopic cholecystectomy
8.	Varicose vein stripping/ligation
9.	Transurethral resection of bladder tumour
10.	Excision of Dupuytren's contracture
11.	Carpal tunnel decompression
12.	Excision of ganglion
13.	Arthroscopy
14.	Bunion operations
15.	Removal of metalware
16.	Extraction of cataract
17.	Correction of squint
18.	Myringotomy with or without grommets
19.	Tonsillectomy
20.	Submucus resection
21.	Reduction of nasal fracture
22.	Correction of bat ears
23.	Dilation and curettage/hysteroscopy
24.	Diagnostic laparoscopy
25.	Termination of pregnancy

Table 1.4 Treatment options for each procedure from BADS Directory of Procedures

Treatment option	Description
Procedure room	Operation that may be performed in a suitable clean environment outside of theatres
Day surgery	Traditional day surgery, discharged without overnight stay
23 h stay	Patient admitted and discharged within 24 h
Under 72 h stay	Patient admitted and discharged within 72 h

Aims

The overall aims of this thesis are:

i) to establish the existing evidence base for day surgery in breast cancer

ii) to evaluate the feasibility of day surgery for breast cancer in Glasgow

iii) to find out whether day surgery is safe, acceptable and advantageous for breast cancer patients within a randomised controlled trial and

iv) to establish key audit outcomes for day surgery in breast cancer

Chapter 2

2.0 Day surgery for breast cancer: A systematic review of the literature

2.1 Introduction

In the General Introduction we saw that over the past decade both breast and axillary surgery have become less invasive prompting earlier discharge after surgery.

2.1.1 Early Discharge Trials

Over the past decade a number of randomised trials compared early discharge with standard care for breast cancer patients. All of these showed either equivalent or better outcomes for early discharge.

Bonnema and colleagues published a paper in 1998 looking at physical and psychological recovery[73] in early discharge patients. They reported high satisfaction rates in early discharge patients and no difference in psychosocial and physical outcomes. Similarly, Bundred and colleagues showed equivalence between early discharge and standard length of stay in physical and psychological outcomes.[74] Women discharged early had less wound pain and better shoulder mobility. Purushotham and colleagues randomised patients into standard versus early discharge without drain insertion. They reported no increase in surgical or psychological recovery.[75]

In another randomised trial, the cost of early discharge was reported to be significantly lower than standard discharge.[76]

All these trials were done in the era where all patients universally had axillary clearances and therefore early discharge patients went home with their drains or had no drains inserted after clearance.

2.2 Aim

The aim of this chapter is to establish, through a systematic review of literature, the benefits and disadvantages of day surgery *versus* inpatient surgery for breast cancer.

2.3 Methods

2.3.1 Sources

The literature search strategy was formulated with the help of a Glasgow University librarian. The Cochrane Library, MEDLINE (including In-Process & Other Non-Indexed Citations), British Nursing Index, CINAHL, EMBASE and PsycINFO were searched between 1966 and September 2008. The search strategy is detailed in Appendix 2.1. Titles of the articles were first screened and abstracts of relevant articles obtained. Full texts of all selected articles were retrieved. The reference lists of obtained articles were hand searched. If any relevant articles were in languages other than English, they were translated.

2.3.2 Study Selection

Studies included needed to fulfil the following criteria:

1. Patients had a diagnosis of breast cancer and underwent true day surgery. Breast Cancer surgery was defined as surgery for both in situ and invasive breast cancers including surgery to the axilla. Day surgery was defined as an operation that allowed the patient to go home later the same day.

2. The study was either a randomised clinical trial or an observational study comparing day surgery and inpatient surgery for breast cancer. An observational study was defined as an aetiology or effectiveness study using data from an existing database, a cross-sectional study, a case series, a case-control design, a design with historical controls, or a cohort design as per the MOOSE guidelines.[77] We excluded review, discussion papers or expert opinion articles from the final analysis, but review articles were checked for additional relevant references.

2.3.3 Outcomes

Data for the following outcomes was extracted:

1. Discharge Outcomes: For patients intended for day surgery we recorded the rate of and reasons for conversion to an inpatient. We also recorded readmission rates after discharge from the day surgery unit for immediate or early post operative complications. We also recorded whether patients who needed further surgery to the breast or axilla had this as a second day case procedure or as inpatients.

2. Physical Outcomes: Nausea, vomiting, pain, wound infection and wound seroma or haematoma rates.

3. Psychosocial Outcomes: Validated quality of life assessments and patient satisfaction questionnaires.

4. Economic Outcomes

2.3.4 Assessment of methodological quality

The full texts of all the relevant articles were independently reviewed and scored by the two authors (VSM and SS).

The methodological quality of the studies was assessed using a checklist that was designed for the assessment of both randomised and non-randomised studies of health care interventions.[78] It was modified to include specific questions relating to the outcome measures above. The checklist (Table 2.1) included information about participants in the studies. Specifically, it included information about whether the whole breast cancer population during the study period was defined and whether their characteristics were clearly described. Pre-assessment criteria for selection of patients for day surgery were studied. The check list also included information about whether outcome information was collected prospectively, and whether it was clearly defined. Also, that the follow up period was adequate to assess the physical outcomes and psychosocial outcomes. Specifically,

follow up to 30 days to assess wound infection according to the CDC (Centre for Disease Control and Prevention) criteria was noted.[79] Information about quality of life and patient satisfaction was included. Re-operation information was extracted where possible. Breast cancer patients may need second operations to their breast (re-excision or mastectomy) if margins are not clear. They may also need further axillary surgery if they have positive nodes on a sentinel node biopsy or axillary sampling. These operations are carried out within a few weeks of the first operation.

From the checklists, studies were then given an overall score. If there was a discrepancy in the scores given by the two reviewers, the papers were discussed and a consensus reached.

2.4 Results

2.4.1 Description of studies

A total of 454 references were identified through the electronic searches of Medline (293), Embase (112), CINAHL (45), BNI (2), PsycINFO (2) and Cochrane (0). Titles of these studies were assessed and 53 relevant abstracts were obtained. After reading through these 53 abstracts, 20 abstracts met our primary inclusion criteria. The full texts of these studies were retrieved. A further five studies were identified after searching through their reference lists. Three of the papers were in languages other than English and were translated to English.[80-82] Eleven of the 25 studies were excluded without being scored for the following reasons: their study population also included benign patients,[83] they were not true day surgery,[84,85] mainly discussed lengths of stay of patients,[86,87] discussed trends of day surgery, [88-90] were review articles[91,92] and one paper addressed the effects of a post surgery telephone survey[93]. Fourteen studies were initially included in the review and scored (Table 2.1). Of these, 3 studies were eventually discarded as they scored poorly (less than 6 out of a maximum of 13) when the methodological quality was rated.[80,94,95] Eleven studies were therefore included in this review.[81,82,96-104] There were no randomised controlled trials found comparing day surgery with inpatient surgery for breast cancer. All the studies included are observational studies.

2.4.2 Methodological quality of the studies

None of the studies measured all the 4 outcomes. The median score obtained by the studies was 6.5 with a range of 2 to 9 (Table 2.1) out of a maximum of 13. Ten studies discussed discharge outcomes and physical outcomes. Patient satisfaction surveys were carried out in seven studies but quality of life was addressed using validated questionnaires in only one study.[101] Economic outcome was discussed in four of the eleven studies.

2.4.3 Participants

Characteristics of the eleven included studies are detailed in Table 2.2. There were five comparative studies and six case series. The duration of the studies ranged from 8 to 108 months. The number of patients ranged from 32 to 625. In seven studies, the total number of breast cancer patients operated on during the study period was clearly defined (Table 2.1). The age of patients ranged from 17 to 90 years. Preassessment criteria used for selection of patients for day surgery are mentioned in eight of the studies (Table 2.1). The main criteria used are fitness for surgery, distance from hospital, social support after surgery and patient choice. In two of the studies, the tumour size (<3cm)[104] and breast conserving surgery (BCS)[97] were used as selection criteria for day surgery. The number of patients declining day surgery in favour of inpatient surgery has been noted in three studies. Two of the studies report 2 and 3 (1.1% and 1.4%) patients declining day surgery[81,99], while one study by Marchal et al[100] reported 38 (13.9%) of patients declining day surgery in favour of inpatient surgery. The surgery performed to the breast (BCS or Mastectomy) and that to the axilla (SNB, Axillary sampling or Axillary Clearance), both varied in the studies (Table 2.2).

An analysis of all the outcome measures considered is detailed below.

2.4.4 Discharge Outcomes

Ten of the papers discussed the rate of conversion from day surgery to overnight stay and the reasons for this (Table 2.3). The rate of discharge from day surgery was very high and ranged from 86 to 100%, with 7 of the 10 studies showing a discharge rate greater than 95%.

Acute readmission rates i.e. readmission with immediate or early postoperative complications after discharge from day surgery was noted in eight of the studies (Table 2.4). Six of the studies stated a 0% readmission rate[81,96,98-100,104] while one study[82] reported a 6% readmission rate (25 patients out of 418) for wound related problems and one[97]

reported a 7% readmission rate (3 procedures out of 45), one patient with nausea and vomiting, one with dyspnoea and one with a wound haematoma.

Three studies discussed re-operation while eight did not. In one study,[96] 24 out of the 165 patients (14%) underwent re-excision or mastectomy and it was not stated whether these were performed as day cases or as inpatient cases. In the study by Carcano et al[97], 7 out of 25 patients (28%) underwent further axillary clearance, of whom 6 had their operation in day surgery setting again. In the third study by Marazzo et al[104], 40 patients out of the 100 (40%) had further surgery. These patients were treated with an axillary clearance as second operation, all done as inpatients.

2.4.5 Physical Outcomes

The incidence of nausea and vomiting ranged from 0.8 to 12.2%.[81,82,96-98,100,102] Most patients were managed with antiemetics and were able to go home. However, intractable vomiting contributed to 0.8 to 5.4% of the overnight admissions (Table 2.3). Post-operative pain control was addressed in 5 studies.[81,82,96,100,102] While adequate analgesic control was achieved in 3 of the studies,[81,96,100] 1 to 2% of the patients needed overnight admission for pain control in the two French studies.[82,100] In both these studies, patients who had undergone axillary clearance were noted to have significantly more pain and needed admission.

Wound infection rates varied from 0 to 16% and other wound related complications such as haematoma or seroma formation ranged from 1 to 22%. Only one study had a 30-day follow-up to check for any wound related problems.[99]

Three of the studies compared the wound complications in the day surgery and inpatient surgery groups (Table 2.5).[82,98,103] Wound infection rates in the day patient groups range from 1% to 1.9% and in the inpatient groups they ranged from 2.4% to 6%. Dravet et al.[82] compared the rate of postoperative seromas in patients who had undergone axillary clearance and found a statistically significant difference between the 2 groups (day

group: 27% vs. inpatient group: 16%). The overall wound complication rates (including wound infection, haematoma and seroma) were found to be similar in both the groups.

2.4.6 Psychosocial Outcomes

Validated quality of life assessment tools were used only by Margolese et al.[101] On a Psychological Distress Scale and an Emotional Adjustment Index, outpatients in this study had less psychological distress (p=<0.09) and better emotional adjustment (p=<0.05).

Seven of the studies had patient satisfaction questionnaires. The questions asked and the methods of scoring were very variable. Four of the papers report high levels of satisfaction amongst 95 to 100% of the patients who underwent day surgery.[81,97,98,104] Marchal et al [100] report an overall mean satisfaction score of 8.97 out of a maximum score of 10, where 10 was the highest level of satisfaction. In two of the studies patients were asked whether they would have day surgery again.[100,101] In the study by Marchal et al[100] 199 (91%) of patients answered yes to this question. Margolese et al[101] report that while 22 of the 55 day patients (40%) would have liked to have spent one night in the hospital rather than going home on the same day, 4 of the 35 inpatients (12%) would have liked the procedure to be done as a day patient rather than staying in.

2.4.7 Economic Outcomes

Four of the studies evaluated the economic outcomes.[97-99,102] Day surgery was found to cost less in all four studies with savings ranging from 40% to 85% when compared to the same operations being carried out as inpatients. Goodman et al[99] in 1993 showed that while the cost of the operations was similar in both outpatient and inpatient groups, the further 2 to 3 days of stay in the hospital added an average cost of $3000. McManus et al[102] compared 110 outpatients with 110 inpatients who either underwent a modified radical mastectomy (n=20) or lumpectomy with axillary dissection (n=90). The savings in the outpatient group per modified radical mastectomy was $4710 and per lumpectomy with axillary dissection was $3827 and showed an overall total potential

savings of $341,430 for 110 patients. Carcano et al[97] showed an average saving of €854 for every outpatient procedure.

2.5 Discussion

From the comparative studies and case series in this review, it seems that day surgery is feasible, safe and maybe beneficial for breast cancer patients. The numbers in individual studies are small and the studies are variable. There is also a lack of good quality of life data in these studies.

There was no clear consensus about pre-assessment criteria. Some studies included medical fitness for surgery while others also considered social support for the patient. Four of the six papers from Europe and UK only included breast conserving surgery patients in their studies, while four of the five studies from North America have included mastectomy patients as well. Day surgery for breast cancer has been practiced in North America since the early 1990s while most studies from the Europe are from the current decade. This is reflected in the papers selected for the present review.

The rate of discharge from the day surgery unit was high in most of the studies. Only three of the studies had overnight admission rates which were greater than 10%. Nausea and vomiting was cited as one of the main reasons for this. Potentially with good antiemetics and adhering to guidelines suggested for ambulatory anaesthesia, this could be controlled.[105] Patient anxiety could be addressed with better preoperative education of the patients. One paper sites over-running theatre lists as a cause for overnight admissions.[96] No study has cited lack of social support as a reason for failed discharge. Readmissions for acute postoperative complications have been very low and none of the complications have been life threatening.

We recognise that some patients undergo a second procedure for their breast cancer which may or may not be performed in Day Surgery. Re-operation surgery may therefore add to the workload of a Day Surgery service. Some patients having re-operation may need an inpatient stay, as mastectomy and axillary clearance are currently not carried out in the UK in a Day Surgery setting.

Nausea, vomiting and pain issues in general appear to be well controlled with medications and in majority of the trials patients were discharged from day surgery. Some of the early discharge studies had attempted to assess the impact of early discharge on General Practitioners in the community. None of the studies in the present review recorded whether patients discharged from day surgery went to their General Practitioners for further advice or for treatment of any postoperative complications and hence we could not assess this. This would have highlighted whether there was any extra burden on the community after discharge of the patient. Further studies should address this as part of evaluation of day surgery. Wound infection rates are variable and appear to be poorly recorded. Only one study had a 30-day follow-up wound surveillance.[99]

Psychosocial outcomes have been very poorly addressed in the studies. Quality of life assessment using validated questionnaires was addressed in only one study[101] and this showed better psychological and emotional adjustment in the day surgery group. In future, use of validated questionnaires to address quality of life issues in a randomised setting should be considered. Patient satisfaction with day surgery in all the studies has been high. None of the papers report dissatisfaction with day surgery. In one study[101] where the patients were asked whether they would have their operation in the same setting as before, 22 of the 55 day patients said they would have wanted one night in hospital and four of the 35 inpatients would have wanted day surgery instead. All the patients in this study were interviewed by phone about 16 to 30 months after their operation retrospectively. Only 90 of the 121 patients (74%) agreed to be interviewed and the researchers depended on the patients' memory of the events and how they felt about them. Clearly this shows that patient satisfaction surveys performed have not been a robust measure of the outcome. Several papers[82,98,100,102] in the present review have also stressed the importance of pre-operative education of patients and their carers coming for day surgery, using various different approaches including written material and educational sessions. This has been

commented to increase the understanding and involvement of the patients and their relatives and hence play a key role in their successful management.

Economic outcomes have mainly been evaluated in the American papers. Clearly the clinical outcomes are paramount, but given clinical equivalence, cost is also an important factor for the NHS.

None of the papers reviewed discussed the issue of post-operative drain management. It is an important issue and has been discussed in papers about early discharge after breast surgery.[74,75] In one of the studies in our review[96] the patients had axillary clearance carried out in Day Surgery but without drains being inserted. Most patients in present practice have either a sentinel node biopsy or axillary node sampling and may not need a drain. However, optimum early follow-up of patients with drains is not clear and may need further study.

The care of a breast cancer patient involves more than just a surgical procedure. They require emotional support, counselling and information about their disease and its management. Currently, as inpatients, women receive support from their surgeon, breast care nurse, ward nurses and interaction with other breast cancer patients in hospital. In the future when more patients have their surgery in a day surgery setting, we need to find new ways to provide this support and information which they would have had in hospital.

2.6 Conclusions

Day surgery for breast cancer appears to be safe and well tolerated with good satisfaction rates. Further research is needed to address both physical and psychological outcomes in randomised controlled trials using appropriate validated questionnaires.

Table 2.1 Checklist to assess the methodological quality of the studies

	Dooley et al[98]	Margolese et al[101]	Seltzer et al[103]	McManus et al[102]	Marrazzo et al[104]	Athey et al[96]	Carcano et al[97]	Marchal et al[100]	Friedman et al[81]	Dravet et al[82]	Goodman et al[99]	Tan et al[94]	Barillari et al[80]	Dalton et al[95]
Is there information about all the breast cancers operated on in the study period from which day surgery patients were selected?	No	Yes	No	No	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	No	No
Are the characteristics of the patients included in the study clearly described?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No
Is it a Comparative Study?	Yes	Yes	Yes	Yes	No	No	No	No	No	Yes	No	No	No	No
Were there proper pre-assessment criteria?	No	No	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
Is the follow-up period adequate?	No	No	No	No	No	Yes	No	No	No	No	No	Yes	No	No
Are the main outcomes to be measured clearly described in the Introduction or Methods section?	No	Yes	No	No	No	Yes	Yes	Yes	No	Yes	No	No	No	No
Were the outcomes assessed prospectively?	Yes	No	Yes	No	No	Yes	Yes	Yes	No	Yes	Yes	No	No	No
Are lengths of stay related issues (discharge rate/reason for overnight stay/readmissions) addressed?	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes
Were Physical Outcomes noted (N/V/Pain/Wound issues)?	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
Was Quality of Life addressed using validated questionnaires?	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No
Were there any patient satisfaction surveys?	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes	No	No	No	Yes	No
Was economic cost evaluated?	Yes	No	No	Yes	No	No	Yes	No	No	No	Yes	No	No	Yes
Were further reoperations for breast cancer noted?	No	No	No	No	Yes	Yes	Yes	No	No	No	No	No	No	No
Overall Score (13)	7	6	6	6	7	9	9	8	6	8	7	3	2	2

Table 2.2 Characteristics of studies included in the systematic review

S. No.	Study	Year	Study design	Patient group	Age (years)*	Duration of study (months)	Type of surgery**	Location
1	Dravet et al[82]	2000	Comparative	625 DP=418, IP=207	Mean age IP = 58 (29-91) DP = 51(20-80)	12	c + f	France
2	Margolese et al [101]	2000	Comparative	90 DP=55, IP=35	Mean age IP=58, DP=57	27	c + e	Canada
3	Seltzer et al[103]	1995	Comparative	178 DP=135, IP=45	Mean age IP=56, DP=55	108	a + e	US
4	McManus et al[102]	1994	Comparative	173 DP=118, IP=55	NR	30	c + e	US
5	Dooley et al[98]	2002	Comparative	87 DP=87, IP=not known	Mean age= 59 (38 to 84)	8	c + f	US
6	Marchal et al[100]	2005	Case series	236	Mean age = 50 (17-76)	12	a + e	France
7	Athey et al[96]	2005	Case series	165	Median age = 55 (39-76)	26	a + f	UK
8	Carcano et al[97]	2005	Case series	32	Mean age = 57 (34-73)	15	a + f	Italy
9	Marrazzo et al[104]	2007	Case series	100	Mean age = 56 (30-82)	16	a + d	Italy
10	Friedman et al[81]	2004	Case series	181	Mean age = 60 (28-92)	33	c + f	Italy
11	Goodman et al[99]	1993	Case series	223	34-90	22	c + e	US

***IP: Inpatient, DP: Day patient**

**Type of surgeries performed: Breast: a: Breast Conserving Surgery, b: Mastectomy, c: Both Breast Conserving Surgery and Mastectomy and Axilla: d: Sentinel Node Biopsy, e: Axillary Clearance, f: Both Sentinel Node Biopsy and Axillary Clearance.

Table 2.3 Rate of discharge from Day Surgery (DS) and reasons for overnight stay

Study	No. of procedures in DS	Rate of discharge from DS - no. (%)	Nausea/ Vomiting - no. (%)	Anxiety/ Patient Choice - no. (%)	Pain Issues - no. (%)	Wound Complications - no. (%)	Medical Complications - no. (%)	Overrunning theatre lists- no. (%)
Seltzer et al[103]	133	133 (100)	-	-	-	-	-	-
Carcano et al[97]	32	32 (100)	-	-	-	-	-	-
Goodman et al[99]	223	223 (100)	-	-	-	-	-	-
Dooley et al[98]	92	91 (99)	-	1 (1.0)	-	-	-	-
Friedman et al[81]	181	179 (99)	-	2 (1.0)	-	-	-	-
McManus et al[102]	118	115 (98)	1 (0.9)	-	-	1 (0.9)	1 (0.9)	-
Marrazzo et al[104]	100	96 (96)	-	4 (4.0)	-	-	-	-
Athey et al[96]	165	149 (90)	2 (0.1)	-	-	1 (0.1)	2 (0.1)	11 (6.7)
Dravet et al[82]	418	366 (88)	19 (4.5)	11 (2.6)	5 (1.2)	11 (2.6)	3 (0.7)	3 (0.7)
Marchal et al[100]	274	236 (86)	16 (5.8)	14 (5.1)	6 (2.2)	2 (0.7)	-	-
Margolese et al [101]	55	-	-	-	-	-	-	-

Table 2.4 Acute readmission rates following discharge from day surgery unit

Study	Acute readmissions
Dooley et al[98]	0
Goodman et al[99]	0
Friedman et al[81]	0
Marchal et al[100]	0
Athey et al[96]	0
Marrazzo et al[104]	0
Dravet et al[82]	25 (7%)
Carcano et al[97]	3 (8%)

Table 2.5 Comparison of wound infection and overall wound complication rates between the day surgery and inpatient surgery groups

	Wound Infection Rates		Overall Wound Complication Rates	
	Day Surgery Group	Inpatient Group	Day Surgery Group	Inpatient Group
Dooley et al[98] (day surgery group = 92, inpatient group number not known)	1%	6%	-	-
Dravet et al[82] (day surgery group = 418, inpatient group = 207)	1.9%	2.4%	6.0%	7.7%
Seltzer et al[103] (day surgery group = 133, inpatient group = 45)	1.5%	4.4%	5.4%	6.6%

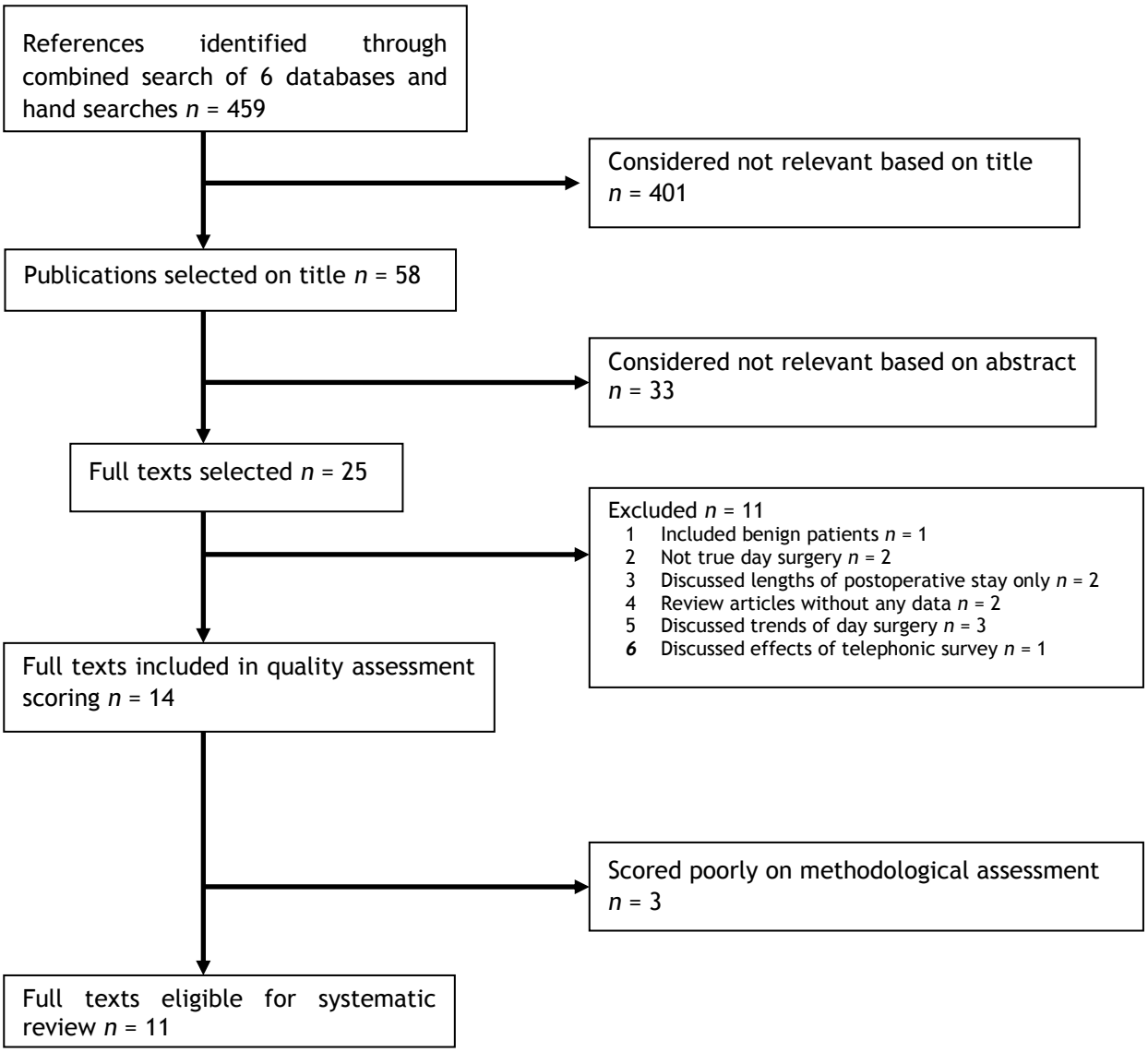

Figure 2.1 Flow chart of articles identified, included and excluded in the systematic review

Chapter 3

3.0 Postoperative length of hospital stay after breast cancer surgery and factors influencing this: Current practise in Glasgow (2007-08)

3.1 Introduction

From the findings of the previous chapter, it appears that day surgery is a safe and feasible option for breast cancer patients. The postoperative length of stay (LOS) after breast cancer surgery and the factors that influence it in the current practise in Glasgow is analysed in this chapter.

3.1.1 Breast cancer population in Glasgow

Patients with breast cancer either present via their General Practitioner to a symptomatic breast clinic in one of the five hospitals or present through the breast screening programme. Over the period of the study, two new Day Hospitals have been built in Glasgow but none of the patients in this study were treated in either. In the West of Scotland, the target screening population is 2,45,000 women which is half the screening population of Scotland. Patients with screen detected cancers are operated on in two designated hospitals if they have non-palpable cancers and in any hospital (designated or local) if they have palpable cancers. All the women studied had primary operable breast cancers. Women treated non-surgically over the study period have not been included.

3.1.2 Length of stay for breast cancer population

With the increasing incidence of breast cancer,[106] the number of admissions to breast units for breast cancer surgery has risen. At the same time, the average LOS for patients with breast cancer has been falling in the UK and other European countries over the past two decades, thus helping in accommodating the increase in number of

admissions.[107] In the UK, the average LOS has fallen from 9.8 days in 1990 to 5.2 days in 2005.[107]

3.1.3 Factors influencing length of stay

Various factors influencing postoperative LOS have been studied for surgical admissions. LOS may be affected by patient factors such as older age, gender, comorbidities and sociodemographics,[108,109] and intraoperative and postoperative adverse events and complications.[109,110] A combination of patient factors and quality of perioperative care have been noted to affect LOS.[109] Specifically, in breast surgery there are few LOS studies and those that exist have studied trends over several decades in LOS for breast cancer surgery.[111-113] The trend towards increasing number of patients undergoing BCS than mastectomy has been universally noted as one of the major factors for the decrease in LOS over the last two decades. The adoption of newer techniques such as axillary sampling and SNB and move towards early discharge have also been shown to be important factors in decreasing LOS.[112] None of the studies have specifically tried to explain the variation in LOS among women having BCS or having mastectomy.

3.2 Aims

The aims of the present study were (i) to record the LOS for patients undergoing breast cancer surgery, (ii) to compare the socio-demographic, clinico-pathologic factors and the LOS in screen detected and symptomatic cancers, (iii) the factors influencing prolonged postoperative LOS in screen detected and symptomatic breast cancers and (iv) the impact of each breast procedure on hospital bed utilisation.

3.3 Methods

The study analysed admissions for surgical procedures carried out for breast cancer at five breast units in Glasgow (Centres A, B, C, D and E). The data of all patients admitted at Victoria Infirmary (Centre A) with a diagnosis of invasive breast cancer or ductal carcinoma in situ (DCIS) undergoing breast surgery over a 12 month period (March 2007 to February 2008) was prospectively collected by a daily record of all admissions and discharges by the researcher on a data base. Data for all surgical admissions and discharges in women with new diagnosis of breast cancer over a six-month period (March to August 2007) for four breast units at Western Infirmary (Centre B), Glasgow Royal Infirmary (Centre C), Stobhill Hospital (Centre D) and Canniesburn Plastic and Reconstructive Surgery Unit (Centre E) was obtained from the PASWEB (Patient Administration System). PASWEB is the software which holds all the admission and discharge data for the patients. The admissions and discharges for all patients are noted each night from all the wards in the hospitals and entered on the PASWEB system. This data is cross checked by clinical effectiveness department. It was used to obtain admission and discharge dates for each patient. LOS was calculated from this information obtained by the researcher. As the researcher was working at one hospital for the whole period of the study, it was feasible for him to prospectively collect data for the whole 12 months, while information for the other hospitals was obtained from hospital databases and it had been feasible to get only 6 months of data. All pathology reports were reviewed to confirm diagnosis through the clinical portal using patient unit numbers. Information about patient comorbidities was obtained from Scottish Medical Record's SMR 01 data form from ISD (Information Services Division) Scotland.

Information recorded on the database included age, socio-demographic factors (deprivation category and distance between patient's residence and the hospital of

operation), patient comorbidity measured using Charlson Comorbidity Index,[114] mode of detection (screen detected or symptomatic), hospital where the operation took place, diagnosis (DCIS or invasive breast cancer), operative procedure performed on the breast and axilla, the tumour size, stage of disease (in situ, early breast cancer and locally advanced or distant disease), and postoperative LOS. Preoperative LOS was recorded but not included in the analysis because almost all patients were admitted the day before surgery and standard methods of measuring hospital LOS are from the time of the index procedure.

Definition of operative procedures: Operative procedures on breast included BCS, mastectomy and mastectomy with some reconstructive procedure. Simultaneously, patients could also have undergone axillary surgery. Surgeries in the axilla included axillary sampling, SNB or axillary clearance. Re-operations included re-excision of the breast lesion and mastectomy, with or without further axillary surgery.

Deprivation category (Depcat) was defined using the Carstair's Deprivation Index.[115]

Definition of prolonged postoperative LOS: Postoperative LOS was defined as the time from the date of the index operation to the date of discharge, transfer to a subacute service or death, whichever came first. A prolonged LOS was defined as a LOS greater than or equal to the 75th percentile for each index operation, including the date of discharge. This definition was in keeping with previous studies.[109,110]

The factors influencing postoperative LOS for all patients were identified after dividing the patients according to mode of detection into screen detected and symptomatic cancers. Independent predictors of postoperative LOS were identified for each group by logistic regression analysis.

3.3.1 Statistical Analysis

Significance of the continuous variable, LOS in screen detected and symptomatic groups was calculated using Mann-Whitney U test. All categorical variables comparing screen detected and symptomatic cancers and factors influencing LOS were compared using X^2 test or Fisher's test as appropriate. A p-value of <0.050 was considered statistically significant. Independent affects of variables found to be significant or nearly significant on univariate analysis for predicting prolonged LOS were assessed using binary logistic regression analysis and presented as odds ratio (OR) with confidence interval (C.I.) and p-value. All statistical analysis was performed using the statistical package SPSS® for Windows® Version 15.0 (SPSS, Chicago, Illinois, USA).

3.4 Results

Over the study period, 519 women underwent surgery for breast cancer at the five centres. There were 252 (49 percent) screen detected and 267 (51 percent) symptomatic cancer patients. The socio-demographic and clinical characteristics of screen detected and symptomatic breast cancer patients are shown in Table 3.1. There was no significant difference in the age or deprivation category distribution in the screen detected and symptomatic cancers. There was a significant difference in the distribution of screen detected and symptomatic cancers across the five centres as all the non-palpable cancers were operated only at Centre A or B ($p<0.001$). The screen detected and symptomatic cancers significantly differed in the Charlson Comorbidity Index scores ($p=0.007$), stage of disease ($p<0.001$) and tumour size ($p<0.001$).

3.4.1 Length of stay after breast surgery

Including all types of surgery, the overall median length of stay for patients was one day (range 0-24) and 50 percent of all patients were discharged within one day of surgery. The median postoperative LOS for screen-detected cancers was one day and for symptomatic cancers it was 4 days ($p<0.001$). There was a significant difference in the number of screen detected and symptomatic patients being discharged within one day of their surgery ($p<0.001$). While 75 percent of screen detected patients were discharged within a day of their operation, 26 percent of symptomatic patients were discharged within a day of their operation.

The median LOS for patients undergoing BCS was one day and the 75^{th} percentile LOS was also one day. The median LOS for mastectomy patients was five days, while the 75^{th} percentile LOS was six days. The median LOS for patients undergoing mastectomy with reconstruction was seven days, and the 75^{th} percentile LOS was 8 days for this group.

The relationship between the socio-demographic and clinico-pathologic factors and postoperative LOS in screen detected cancers is shown in Table 3.2. Factors found to be significantly associated with prolonged LOS on univariate analysis were the axillary procedure ($p<0.001$), the tumour size ($p=0.007$) and the cancer stage ($p=0.016$). Multivariate analysis of these factors (Table 3.4) shows that the axillary procedure performed (odds ratio = 5.61, $p<0.001$) and the tumour size (odds ratio = 1.61, $p=0.059$) independently influenced prolonged postoperative LOS.

The relationship between the socio-demographic and clinico-pathologic factors and postoperative LOS in symptomatic cancers is shown in Table 3.3. Factors found to be significantly associated with prolonged LOS on univariate analysis were the deprivation category ($p=0.008$), the breast procedure ($p=0.026$) and the axillary procedure ($p<0.010$). Multivariate analysis of all factors nearing significance ($p<0.1$) shows (Table 3.4) that the axillary procedure performed (odds ratio = 2.06, $p=0.002$), the Charlson Comorbidity Score (odds ratio = 1.74, $p=0.049$) and the deprivation category (odds ratio = 1.48, $p=0.045$) independently influenced prolonged postoperative LOS.

3.4.2 Hospital bed utilisation

A more detailed study of all the procedures performed at Centre A shows that 185 patients (63 percent) underwent breast conserving surgery with or without axillary surgery (BCS ± SNB/Axillary Sampling/Axillary Clearance) and had a median length of stay of one day (Table 3.5). They utilised 256 hospital bed days (29 percent). Sixty six patients (23 percent) underwent mastectomy with or without axillary surgery (Mastectomy ± SNB/Axillary Sampling/Axillary Clearance) and utilised 451 hospital bed days (51 percent). Forty two re-operations (14 percent) were performed with the patients having a median length of stay of 4 days. These patients utilised a further 175 hospital bed days (20 percent). The most common re-operation procedures performed

(19 patients) were axillary clearance with or without further surgery to the breast (RE or mastectomy). Of the 175 hospital bed days, these patients utilised 121 hospital bed days. Nineteen patients underwent re-excision with or without axillary sampling and utilised 37 hospital bed days, 2 patients underwent mastectomy alone and added 13 days while 2 patients had wound problems and added 4 days.

3.5 Discussion

This study of postoperative LOS after breast cancer surgery in Glasgow shows that in 2007-08, 50 percent of the patients were discharged from hospital within a day of their operation. (Table 3.1) This suggests that, potentially 50 percent of the patients undergoing breast cancer surgery in the present setting could be considered for treatment in a day surgery or 23-hour care facility. However, not all the 50 percent would have passed the day surgery pre-assessment criteria. Although in practise they were discharged after one day, they may not have been suitable for day surgery. Some of these patients, for example, may have had comorbidities which would mean their surgical team were happier to treat them as inpatients, even though in the event they were fine, they would go home the next day after surgery. Similarly, some fit and healthy women currently staying in for four days with a drain would be potentially suitable for day surgery or 23-hour care, going home with or without a drain.

The postoperative LOS was significantly different in screen detected and symptomatic cancer patients. (Table 3.1) It is well established that breast screening helps detect cancers at an earlier stage[4,116,117] and screen detected cancers more frequently undergo BCS procedures.[118] In the present study, the difference in postoperative LOS can be attributed to the difference in the stage of disease at presentation. Larger tumour size and more advanced disease meant that patients in the symptomatic group had more extensive surgery and stayed longer in hospital postoperatively. A higher proportion of patients in the symptomatic group were noted to be from the more deprived areas compared to the screen detected cancer group (38% vs 24%), although this was not statistically significant. This is in keeping with the national trends.[4] In Glasgow, the screen detected cancers are referred to Centre A and B and hence the distribution of screen detected and symptomatic cancers shows variation across the centres.

The overall level of comorbidity amongst women undergoing operative treatment for breast cancer was very low (11 percent). There was a significant difference in the incidence of comorbidities between the screen detected and symptomatic cancer groups, suggesting that the cohort of screen detected cancers is different from the symptomatic cancers. The screen detected cancer patients are more likely to be healthier and have earlier stage disease. But, the fact that few patients had significant comorbidities is encouraging and would support the possibility that majority of patients would be suitable for day surgery. Data on comorbidity was obtained from SMR01 data which is collected uniformly on every hospital admission in Scotland. Morbidities are ranked with breast cancer as the first comorbidity with up to the first six comorbidities being recorded. It is very accurate information which is regularly audited. If this study was to be repeated, in addition to the SMR01 information, perhaps more detailed information about the patients' functioning at home should be collected.

In view of this difference between the screen detected and symptomatic cancers, the factors influencing the postoperative LOS in these two groups were studied separately.

In the screen detected cancers, the sociodemographic factors (age, deprivation and distance from hospital) and patient comorbidities did not have a statistically significant affect on prolonged LOS. Tumour characteristics which were statistically associated with prolonged LOS were the axillary procedure and the size of tumour. While the size of tumour was noted to have some affect on prolonged LOS (odds ratio = 1.61, $p=0.059$), the axillary procedure had the maximum affect (odds ratio = 5.61, $p<0.001$) and appears to be the most important factor in determining LOS in the screen detected cancer patients. Majority of the patients in this group had breast conserving surgery (213 of the 252 patients) and it is known that screen detected cancers are less

likely to have axillary nodal involvement and hence tend to have less extensive axillary procedures. However, if these patients undergo axillary clearance, it affects their LOS significantly.

In the symptomatic cancers, the axillary procedure (odds ration = 2.06, p=0.002), comorbidity (odds ratio = 1.74, p=0.049) and the deprivation category (odds ratio = 1.48, p=0.045) were found to have a statistically significant affect on prolonged LOS. Although the effect of the axillary procedure was not as significant as the screen detected group, it was still the most important determinant. More patients in this group had associated comorbidities and this had some affect on the LOS. Thirty nine percent of patients in the most deprived categories had a prolonged LOS compared to 23 percent and 19 percent in the other categories. Therefore, we note that while comorbidities and deprivation category do not influence LOS in the screen detected cancers, they have some influence on the LOS in the symptomatic cancers.

When we analysed the patient population at Centre A to ascertain the overall effect of each procedure on the cumulative hospital bed occupancy, mastectomies contributed more than 50 percent to this while breast conserving surgery patients contributed 29 percent. Forty two patients (14 percent) underwent reoperations and contributed a further 20 percent to the bed occupancy. The majority of patients in this group were patients who had previously undergone breast conserving surgery and needed further surgery to the breast (re-excision or mastectomy) and/or to the axilla (axillary clearance). Majority of patients in this group stayed in hospital for ≥2 days and they may not be suitable for reoperation in a day surgery setting. Axillary clearance seemed to be the most important factor contributing 121 of the 175 days that the re-operations added.

Overall, the axillary procedure performed appears to be the most important determinant of prolonged LOS. All the patients who underwent an axillary clearance

had an axillary drain inserted which is the most important contributor to these patients' prolonged LOS. Many studies have attempted to reduce the LOS by either sending patients home with a drain in situ,[119,120] or by not inserting a drain at all,[75,96,121] with safe outcomes. Sending patients home with the drain in situ is a feasible option for our patients but would require patient education and support from the community nurse. This needs to be assessed further.

3.6 Conclusions

In conclusion, we note that in our current practise in Glasgow, 50 percent of the women having operations for breast cancer as inpatients were discharged within one day postoperatively. Most of these would have been suitable for day surgery and the rest potentially for 23-hour care within a day surgery hospital. Some of these patients will still need a second inpatient admission for reoperation. These readmissions as inpatients need to feature in planning a day surgery service.

Axillary procedure appears to be the main determinant of prolonged LOS. Sending patients home with a drain in situ may be an option which needs to be considered in these women.

While patients undergoing mastectomies with or without axillary surgery contribute to half of the bed occupancy, a further 20 percent is contributed by re-operations.

Table 3.1 Socio-demographic and clinical characteristics of screen detected and symptomatic breast cancer patients

		Screen Detected Cancers (%)	Symptomatic Cancers (%)	Total (%)	p value
Number of patients		252 (49)	267 (51)	519	
Factors	Categories				
Age (years)	<50	0 (0)	68 (26)	68 (13)	
	50 - 69	216 (86)	109 (41)	325 (63)	
	>70	36 (14)	90 (34)	124 (27)	0.253
Deprivation category	Group 1 (Depcat 1/2)	43 (17)	57 (21)	100 (19)	
	Group 2 (Depcat 3/4/5)	149 (59)	108 (40)	257 (50)	
	Group 3 (Depcat 6/7)	60 (24)	102 (38)	162 (31)	0.101
Centre	A	168 (67)	83 (31)	251 (48)	
	B	69 (27)	54 (20)	123 (24)	
	C	0 (0)	50 (19)	50 (10)	
	D	0 (0)	46 (17)	46 (9)	
	E	15 (6)	34 (13)	49 (9)	<0.001
Charlson Comorbidity Index Score	0	232 (92)	231 (87)	463 (89)	
	1	19 (8)	25 (9)	44 (9)	
	2	1 (0)	9 (3)	10 (2)	
	3	0 (0)	2 (1)	2 (0)	0.007
Stage of disease	in situ	69 (27)	18 (7)	87 (17)	
	early breast cancer	181 (72)	204 (76)	385 (74)	
	locally adv./metastatic	2 (1)	45 (17)	47 (9)	<0.001
Tumour Size (mm)	<10	63 (36)	19 (9)	82 (41)	
	11-20	89 (51)	84 (38))	173 (44)	
	20-30	18 (10)	72 (33)	90 (23)	
	>30	4 (2)	44 (20)	48 (12)	<0.001
LOS (days)	Median	1 (0 -13)	4 (0-24)	1 (0-24)	<0.001*
	≤1 day	190 (75)	70 (26)	260 (50)	
	>1 day	62 (25)	197 (74)	259 (50)	<0.001

*Mann-Whitney U test

Table 3.2 The relationship between socio-demographic and clinico-pathologic factors and postoperative LOS in Screen Detected Cancers: Univariate Analysis

Factors	Categories	Subgroup total (n)	Normal LOS $\leq 75^{th}$ centile (%)	Prolonged LOS $>75^{th}$ centile (%)	p value
Age (years)	50 - 69	216	189 (88)	27 (13)	
	>70	36	29 (81)	7 (19)	0.190
Deprivation category	Group 1 (Depcat 1/2)	43	36 (84)	7 (16)	
	Group 2 (Depcat 3/4/5)	149	133 (89)	16 (11)	
	Group 3 (Depcat 6/7)	60	49 (82)	11 (18)	0.621
Distance from Hospital	0 - 10 miles	151	128 (85)	23 (15)	
	11 - 20 miles	64	57 (89)	7 (11)	
	21 - 50 miles	34	30 (88)	4 (12)	
	>50 miles	3	3 (100)	0 (0)	0.334
Hospital	A	168	143 (85)	25 (15)	
	B	69	62 (90)	7 (10)	
	E	15	13 (87)	2 (13)	0.652
Charlson Comorbidity Score	0	232	203 (88)	29 (13)	
	1	19	14 (74)	5 (26)	
	2	1	1 (100)	0 (0)	0.170
Breast Procedure	BCS	213	189 (89)	24 (11)	
	Mx	22	15 (68)	7 (32)	
	Mx with reconstruction	17	14 (82)	3 (18)	0.147
Axillary Procedure	No procedure*	75	70 (93)	5 (7)	
	AS/SNB	162	142 (88)	20 (12)	
	AC	15	6 (40)	9 (60)	<0.001
Tumour size	≤10 mm	88	81 (92)	7 (8)	
	11 – 20 mm	109	94 (86)	15 (14)	
	21 – 30 mm	26	20 (77)	6 (23)	
	>30 mm	9	6 (67)	3 (33)	0.007
Cancer stage	in situ	69	65 (94)	4 (6)	
	early breast cancer	181	152 (84)	29 (16)	
	locally adv./ metastatic	2	1 (50)	1 (50)	0.016

*No axillary procedure group: 58 DCIS, 17 Cancers (3 patients had previous axillary procedures and 14 patients underwent axillary procedures at subsequent operations)

BCS=breast conserving surgery, Mx=mastectomy,
AS=axillary sampling, AC=axillary clearance, SNB=sentinel node biopsy

Table 3.3 The relationship between socio-demographic and clinico-pathological factors and postoperative LOS in Symptomatic Cancers: Univariate Analysis

Factors	Categories	Subgroup total (n)	Normal LOS ≤75th centile (%)	Prolonged LOS >75th centile (%)	p value
Age (years)	<50	68	49 (72)	19 (28)	
	50 - 69	109	78 (72)	31 (28)	
	>70	90	66 (73)	24 (27)	0.845
Deprivation category	Group 1 (Depcat 1/2)	57	44 (77)	13 (23)	
	Group 2 (Depcat 3/4/5)	108	87 (81)	21 (19)	
	Group 3 (Depcat 6/7)	102	62 (61)	40 (39)	0.008
Distance from Hospital	0 - 10 miles	239	171 (72)	68 (29)	
	11 - 20 miles	13	11 (85)	2 (15)	
	21 - 50 miles	6	4 (67)	2 (33)	
	>50 miles	9	7 (78)	2 (22)	0.605
Hospital	A	83	58 (70)	25 (30)	
	B	54	40 (74)	14 (26)	
	C	50	39 (78)	11 (22)	
	D	46	29 (63)	17 (37)	
	E	34	27 (79)	7 (21)	0.725
Charlson Comorbidity Score	0	231	170 (74)	61 (26)	
	1	25	18 (72)	7 (28)	
	2	9	4 (44)	5 (56)	
	3	2	1 (50)	1 (50)	0.087
Breast Procedure	BCS	114	69 (61)	45 (40)	
	Mx	117	95 (81)	22 (19)	
	Mx with reconstruction	36	29 (81)	7 (19)	0.026
Axillary Procedure	No procedure*	38	32 (84)	6 (16)	
	AS/SNB	85	66 (78)	19 (22)	
	AC	144	95 (66)	49 (34)	0.010
Tumour size	≤10 mm	21	16 (76)	5 (24)	
	11 – 20 mm	90	63 (70)	27 (30)	
	21 – 30 mm	73	49 (67)	24 (33)	
	>30 mm	45	34 (76)	11 (24)	0.930
Cancer stage	in situ	18	15 (83)	3 (17)	
	early breast cancer	204	147 (72)	57 (28)	
	locally adv./ metastatic	45	31 (69)	14 (31)	0.312

* No axillary procedure group: 11 DCIS, 27 Cancers (14 had previous axillary surgery, 7 underwent axillary procedures at subsequent operations and 6 had simple mastectomies)

BCS=breast conserving surgery, Mx=mastectomy,

AS=axillary sampling, AC=axillary clearance, SNB=sentinel node biopsy

Table 3.4 The relationship between socio-demographic and clinico-pathological factors and postoperative LOS in Screen Detected and Symptomatic Cancers: Multivariate Analysis

Group	Factor	odds ratio (95% CI)	p value
Screen detected cancer group	Axillary procedure	5.61 (2.24 – 14.06)	<0.001
	Tumour size	1.61 (0.98 – 2.636)	0.059
Symptomatic cancer group	Axillary procedure	2.06 (1.30 – 3.29)	0.002
	Charlson Comorbidity Score	1.74 (1.00 – 3.06)	0.049
	Depcat	1.48 (1.01 – 2.17)	0.045

Table 3.5 Procedures performed, length of postoperative hospital stay and impact on cumulative hospital bed days at Hospital A

Procedure	n (%)	Median LOS (Range)	Cumulative hospital bed days (%)
BCS ± AS/SNB/AC	185 (63)	1 (0-8)	256 (29)
Mx ± AS/SNB/AC	66 (23)	6 (1-24)	451 (51)
Re-operations	42 (14)	4 (1-13)	175 (20)
Total	293	1 (0-24)	882

BCS=breast conserving surgery, Mx=mastectomy,

AS=axillary sampling, AC=axillary clearance, SNB=sentinel node biopsy

Chapter 4

4.0 A pilot randomized controlled trial comparing day surgery with inpatient surgery for breast cancer patients undergoing breast conserving surgery with axillary sampling or sentinel node biopsy

4.1 Introduction

It was noted in the last chapter that potentially about 50 percent of women in Glasgow undergoing surgery for breast cancer would be suitable for day surgery. However, just because they are suitable does not necessarily mean day surgery would be the best option for them. In the systematic review in Chapter 2, day surgery for breast cancer appeared to be safe and well tolerated with good patient satisfaction rates. However, all the studies in the systematic review were observational studies. In the world literature, no randomised controlled trials of day surgery for breast cancer were found. None of the studies had used validated questionnaires to measure either physical or psycho-social outcomes.

4.2 Aim

The aim of this study was to establish in a pilot randomised controlled trial whether day surgery improved physical and quality of life outcomes in breast cancer patients undergoing breast conserving surgery with axillary sampling or sentinel node biopsy compared with inpatient surgery.

4.3 Methods

The trial was conducted at the breast units of two hospitals in Glasgow. The study received ethical approval from the Local Research Ethics Committee. Patients with newly diagnosed invasive breast cancer undergoing BCS with axillary sampling or SNB, who passed the day surgery preassessment criteria (Appendix 4.1), were considered eligible for inclusion in the study. Patients undergoing mastectomy and/or axillary clearance were excluded from the study. Potentially eligible patients had an initial discussion about the trial with their consultant surgeon and then were handed a patient information sheet (Appendix 4.2) to take home. They were given a minimum of 24 hours to think about it. If agreeable, the patients were consented (Appendix 4.3) for the trial by another visit to the hospital. Randomisation to inpatient surgery or day surgery was carried out by the researcher using sealed envelopes in blocks of four. The envelopes were stratified for the hospital but not the procedure.

Patients randomised to inpatient surgery were admitted to a surgical ward the evening before their operation and discharged home on first postoperative day if well. This was the normal practice for all breast cancer patients at these hospitals. Patients randomised to day surgery had their operation at a Day Surgery Unit. They were admitted on the day of their surgery at 1 pm and all being well, discharged home by 6 pm the same evening.

The operations were performed by three of the four surgeons in the two hospitals, whether as inpatients or as day surgery. The anaesthetic management of the patients was also similar. None of the patients received any prophylactic antibiotic cover. All patients had a long acting local anaesthetic agent infiltrated into their wounds at the end of their surgery. Patients discharged from the day surgery unit had a wound check by the district nurse the following day. Protocols for admission to the ward were in place in the event of a problem occurring. Patients in the day surgery group would need admission to hospital

after surgery, if they had a drain inserted at the time of their operation or if they had uncontrolled postoperative nausea and vomiting (PONV). Any readmission to the hospital after discharge due to a postoperative complication was also to be noted. Patients were followed up for a period of 30 days after their surgery.

The primary outcome measures were physical. Physical outcomes assessed included surgical site infections (SSIs), other wound related complications, PONV, pain and physical activity post surgery. The secondary outcome was quality of life, which was assessed using a FACT B (Functional Assessment of Cancer Therapy Breast) quality of life questionnaire.[122]

4.3.1 Surgical Site Infection Form

Surgical site infections were recorded using a validated SSI form (Appendix 4.4) on Day 7 and Day 30 after surgery.[123] They were recorded on the form on Day 7 by visual inspection of the wound by the operating surgeon at the postoperative results clinic and on Day 30 by telephone conversation with the patient to ask if they had been seen by a general practitioner or a district nurse and noted to have an infection and started on antibiotics.

4.3.2 Patient Diary

To assess day to day changes in the patient's physical activity, pain, and PONV, a patient diary (Appendix 4.5) was designed where all these parameters were recorded on linear analogue scales for the first seven days postoperatively. A daily record was maintained by the patients on scales marked 0 for none to 100 for maximum. They also recorded their daily physical activity and whether they had stepped out of their house. This was used as a marker for physical activity. The patients also noted daily if they took painkillers. At the end of the week, patient satisfaction with the experience was checked by asking them if they would choose the same way of treatment again and whether they would recommend day or inpatient surgery to a friend. Patients were given space in the diary to write their own comments and feedback about their experience.

4.3.3 FACT B Questionnaire

FACT B questionnaire is a validated breast cancer specific health related quality of life questionnaire.[122] The FACT B questionnaire was selected for the study after discussion with a Macmillan Consultant in Psychosocial Oncology (Prof. Craig White) who is also a member of the SIGN guideline development group for Breast Cancer.[124] The FACT B questionnaire (Appendix 4.6) was filled in by the patients firstly after they gave consent for the trial and again on Day 7 and Day 30 after surgery to obtain scores at baseline and 2 time points after surgery for longitudinal comparison. The FACT B questionnaire consists of a FACT G (General) component which comprises 27 items and a Breast Cancer Subscale with nine items specific to quality of life in breast cancer.[122] FACT G is sub-divided into four subscales assessing Physical Well-Being (PWB), Emotional Well-Being (EWB), Social Well-Being (SWB) and Functional Well-Being (FWB). The questionnaire is for self-administration using a 5-point Likert rating scale from 0 (Not at all) to 4 (Very much). A lower score indicates poorer quality of life.

Patient demographics including age and social deprivation categories (Carstairs deprivation index) were recorded.[125] Tumour characteristics were recorded, including type, grade, nodal status and Nottingham Prognostic Index (NPI). [126]

4.3.4 Statistics Analysis

Before starting the trial, the feasibility of performing BCS with axillary sampling or SNB as a day case was assessed by carrying out five cases in the day surgery unit. The five cases performed as day cases went well and the patients had no problems in going home the same evening. The only issue highlighted was the quality of postoperative instructions given with regards to arm exercises. The nurses in the day surgery unit were then trained regarding the information needed to be given to the patients and patients were given written information about arm exercises in the trial. A survey of 30 inpatients was also carried out asking their views about having their operation as a day case, had they

been offered it. This showed that 19 of the 30 women interviewed in the wards would have been interested in day surgery if it had been offered. As no previous randomised trial had been performed to address day surgery for breast cancer, we were unable to power the study.

Data are presented as median and range. Where appropriate, differences between the inpatient group and the day surgery group data were tested for statistical significance using the Mann-Whitney U-test and chi square test or Fisher's exact test as appropriate. Data from different time periods within each group were tested for statistical significance using Wilcoxon signed rank test (SPSS version 15.0, SPSS Inc., Chicago, Illinois).

4.4 Results

The trial was carried out over a 12-month period from March 2007 to March 2008. Over the trial period a total of 231 new invasive breast cancers were diagnosed. Of these, 92 (40%) patients underwent either mastectomy or axillary clearance or both and hence were excluded from the trial. The remaining 139 (60%) patients underwent BCS with axillary sampling or SNB and therefore were potentially eligible for the trial. From this cohort of 139 patients, 50 (36%) were actually assessed for eligibility. (Figure 4.1) Of these, 19 patients were excluded: 11 failed preassessment (5 due to medical problems, 4 due to high BMI and 2 due to social problems) and 8 were excluded for other reasons. In 6 cases, the trial was not discussed with potentially eligible patients due to lack of spaces in day surgery for the next few weeks and in 2 cases, the patients were thought to be too anxious to cope with a trial by the breast care nurses. Thirty one patients were included in this pilot study. Of these, 15 and 16 were randomised to the inpatient and the day surgery groups respectively. One patient was cancelled due to unavailability of radiological localisation services on the day and one got missed due to an administrative error and failed to receive any forms. One patient in the inpatient group and 2 in the day surgery group failed to return their Day 30 FACT B form.

4.4.1 Baseline characteristics

The baseline characteristics of the patients at the study entry point are detailed in Table 4.1. Both groups were similar for age, social background and tumour characteristics. All patients underwent BCS with either axillary sampling or SNB. None of the patients had any drains inserted at the end of their procedure. All inpatients were discharged on the first postoperative day and all day surgery patients were discharged within four hours of their procedure. None of them had any immediate or delayed postoperative complications such as haemorrhage requiring them to go back to theatre or be readmitted to the hospital after discharge.

4.4.2 Physical Outcomes

Two patients in the inpatient and one in the day surgery group developed surgical site infections within the first seven days post operatively. There were no SSIs between Day 7 and Day 30. Other physical outcomes obtained from the Patient Diary show similar results for all the parameters in both the groups. (Table 4.2) Six patients had PONV in the first 24 hours after their surgery. Of these, two patients (one inpatient and one day patient) had PONV till the third postoperative day. Patients' pain scores as recorded on a linear analogue scale showed significant improvements within the groups during the first week but no significant difference was noted between the 2 groups.

4.4.3 FACT B scores

The subgroup, FACT G and FACT B baseline scores were similar in both the groups. (Table 4.3)

In comparison to baseline scores, there was a significant fall in the FACT B scores (indicating poorer quality of life) in the inpatient group by postoperative Day 7. (Table 4.4) There was also a significant difference in the FACT G ($p = 0.036$) and FACT B ($p=0.045$) scores between the inpatient and the day surgery group by Day 7.

Thirty days after surgery, a repeat scoring of the FACT B questionnaire did not show any significant difference for the scores compared to the baseline scores and there were no significant differences seen between the two groups. (Table 4.5)

4.4.4 Patient satisfaction

At the end of the first week, patients were asked, if they would have the operation in the same setting again and whether they would recommend the same type of care (inpatient or day surgery) to a friend. There was no difference in the two groups with all patients staying loyal to the type of care they received. There were a few interesting comments in the space provided for free-text in the patient diary, interestingly all from

patients in the day surgery group: ‘I think day surgery suited me because it didn’t make me feel like a “patient”, ‘I enjoyed the aftercare in the comfort of my home’ and ‘discussion with breast care nurse was informative and also good to have a face and a name for future references’.

The present study demonstrates that BCS with axillary sampling or SNB can be safely performed in day surgery and that day surgery patients have significantly better quality of life by the end of the first postoperative week.

4.5 Discussion

To our knowledge, this study is the first randomised controlled trial comparing day surgery and inpatient surgery in breast cancer patients. The results confirm the findings of previous observational studies which have found day surgery for breast cancer to be safe and well tolerated with good satisfaction rates, as has been seen in the systematic review conducted by the researcher.[127] However, despite this, there have been worries about introducing day surgery for breast cancer patients. These worries have centred on the issues of patient support and psychological adjustment. Without time in hospital, would patients have more difficulties coping with their cancer diagnosis? Or, would it be possible to provide the same level of support for women as day cases that they currently get as inpatients? In the USA, for example, the idea of 'drive through mastectomies' has been debated in the literature.[128] Locally, while carrying out this study, there were worries about these issues from several members of our breast team. The present study was therefore conducted to check the feasibility and acceptability of day surgery in our breast cancer population and to obtain a feedback from them.

Three patients (10 percent) in this study, (two inpatients and one day surgery patient) developed SSIs. These patients were managed in the community with oral antibiotics and did not need readmission to the hospital. This is a higher rate than reported for 'clean surgery'. SSIs have been noted to be higher in breast cancer surgery compared to other clean surgeries.[129] A Cochrane review and SIGN guidelines suggest that prophylactic antibiotics do reduce the risk of SSIs in patients undergoing surgery for breast cancer.[130,131] In our study, none of the patients had prophylactic antibiotics. Previous studies involving surgical patients undergoing mainly clean procedures have suggested lower incidence of SSIs in day surgery patients compared to inpatients.[132,133] This difference could be due to a bias towards relatively fitter patients being operated in day surgery. These patients are also at lower risk of SSIs as they may be undergoing smaller

procedures. There may also be ascertainment bias in the published day surgery literature, in that, for some general surgical day surgery studies, SSI surveillance was not carried out to 30 days and was done using varying methods. With the small numbers in the present study, it is difficult to comment on these issues based on our results.

PONV and pain were well controlled with medication after discharge and none of the patients had a prolonged stay or readmission for these issues. We noted PONV in 6 of the 29 patients. The incidence of PONV after breast surgery in the early 1990s was reported to be as high as 50 percent.[134] With the use of prophylactic combination antiemetics, this has fallen to between 10 to 20 percent,[135] which is similar to what we see in our study. As all patients in our trial underwent BCS and axillary sampling or SNB, pain control was in general very good in both the groups. Patients seemed to be more physically active in the day surgery group with more frequently stepping out of their house, and this was noted to be nearing statistical significance (p=0.085). It would be of interest to note if the trend continues in a larger trial.

There was significant difference noted in the FACT B scores 7 days postoperatively between the two groups. (Table 4.4) Scores for inpatients dropped more, relative to the day surgery group. A FACT B interpretation paper suggested that the minimum important difference between endpoint scores obtained at different time points was 5 to 6 percent.[136] The median scores for FACT G and FACT B dropped by greater than 10 percent in the inpatient group compared to 2 to 3 percent for the day surgery group seven days postoperatively. Looking at the individual subgroups scores of FACT B, we have noticed a significant difference between our two groups in the subgroups of PWB and EWB. (Table 4.4) The PWB subgroup includes questions about energy levels, nausea, pain and feeling ill. The EWB subgroup includes questions about coping with illness, losing hope, feeling sad and worrying about dying. There was little difference in the FWB and SWB subgroups where the questions were more general and about family and social support.

The questions in the Breast Cancer Subscale were directed more at long term effects of surgery and chemo-radiotherapy and there was no difference noted in the groups. Our day surgery patients therefore seemed to cope better with physical symptoms after surgery itself and also with their diagnosis of cancer at least in the first week. It has been previously suggested that day surgery patients tend to 'downgrade the seriousness of the operation' and in doing so have a much better mental attitude towards recovery.[99] The above results would support this view. A repeat evaluation of the FACT B questionnaire 30 days after surgery shows patients in both the groups to have recovered back to baseline levels.

Patient satisfaction was also measured by asking patients if, given a chance they would have the operation again in the same setting and if they would recommend the type of care to a friend. Universally all patients stayed loyal to their type of care. This suggests patient satisfaction with either type of care received to be high.

Of the 139 potentially eligible patients, 50 (36%) were actually screened for the trial. Eighty nine patients were therefore not assessed for the trial. A quarter of these 89 patients were seen by the one local surgeon not taking part in the trial. Patients in the trial had their initial appointment with one of the three other consultants. Some patients were missed when these consultants were oncall, on holiday or too busy to discuss the trial. Other patients were probably missed because some team members were anxious themselves about putting patients forward for potential day surgery. As the year went on, everyone became more confident about the idea as the patients themselves were enthusiastic about day surgery. In some cases the reason was not recorded for why the patient had not been approached.

Of the 50 patients screened, 19 were excluded. These exclusions may not be necessary in the future. Eleven patients failed day surgery preassessment, 2 of these were for social problems and 4 due to high BMIs. By the end of the year, we would not have

excluded patients for social reasons. Similarly, the BMI criteria had a cut-off of 35, while for other specialties it is 40. This cut-off criterion could be adjusted. The 5 patients excluded for medical reasons could now have the opportunity to spend the postoperative night in a 23-hour bed in our day surgery unit.

4.6 Conclusions

In conclusion, although in this pilot study the actual study population is small, day surgery for BCS appears to be feasible and highly acceptable amongst patients. When compared to inpatients, day surgery patients appeared to have equivalent physical outcomes and better quality of life outcomes by the end of the first week post surgery. A larger randomised controlled trial may be planned based on the results of this pilot study to confirm these results.

Table 4.1 Baseline characteristics of Breast Cancer patients in the trial

	Inpatient Group n=14	Day Patient Group n=15	p value
Age (years)	55.5 (45 to 69)	59 (41 to 69)	0.584
Axillary Sampling/SNB	12/2	14/1	0.473
Depcat	4 (1 – 7)	5 (1 – 7)	0.453
Tumour Size (mm)	14 (5 to 27)	12 (7 to 24)	0.264
Number of nodes removed	4 (1 to 6)	5 (1 to 8)	0.079
Number of positive nodes	0 (0)	0 (0 to 1)	0.164
Estrogen Receptor Status	8 (0 to 8)	8 (0 to 8)	0.251
Progestorone Receptor Status	8 (0 to 8)	6 (0 to 8)	0.745
HER2 Receptor Status	All negative	All negative	
NPI (Nottingham Prognostic Index)	3.32 (2.18 to 4.54)	3.20 (2.14 to 5.26)	0.336

Table 4.2 Results obtained from the Patient Diary for the first 7 days

	Inpatient Group n=14	Day Patient Group n=15	p value
Wound Infection (n)	2	1	0.181
PONV (n)	4	2	0.372
Painkillers taken till (Day)	7 (2 to 7)	5 (2 to 7)	0.372
Pain Scores D1	40 (15 to 90)	50 (20 to 70)	0.292
Differential Pain Scores (D4-D1)	-20 (-80 to 10)**	-10 (-40 to 20)*	0.833
Differential Pain Scores (D7-D1)	-20 (-80 to 20)*	-30 (-70 to 25)**	0.624
First stepped out of house (Day)	3 (1 to 7)	2 (1 to 6)	0.358
No. of days out in 1st week (days)	3 (1 to 6)	4 (2 to 7)	0.085

*p<0.05, **p<0.01

Day = Postoperative day

D4-D1 = Difference of Postoperative scores (Day 4 – Day 1)

D7-D1 = Difference of Postoperative scores (Day 7 – Day 1)

Table 4.3 Baseline FACT B scores for the inpatient and the day patient groups

	Inpatient Group n=14	Day Patient Group n=15	p value
Physical Well Being	27 (23 to 28)	26 (20 to 28)	0.382
Social Well Being	26 (17 to 28)	25.7 (18.7 to 28)	0.739
Emotional Well Being	19.1 (11 to 24)	18 (2 to 24)	0.630
Functional Well Being	24 (18 to 27)	26 (20 to 28)	0.913
Breast Cancer Subscale	30.2 (22.5 to 34)	26 (15 to 35)	0.042
FACT G	96.4 (73 to105)	90 (69.6 to 108)	0.458
FACT B	126.2 (104.5 to 138)	118 (89.1 to 143)	0.106

Table 4.4 Changes in FACT B scores, 7 days post surgery

Differential Scores (Day 7 – Day 1)	Inpatient Group n=14	Day Patient Group n=15	p value
Physical Well Being	-4.0 (-20.0 to -1.0)**	-2.0 (-5.0 to 3.0)*	0.029
Social Well Being	0.0 (-9.3 to 11.0)	-1.0 (-10.5 to 8.4)	0.963
Emotional Well Being	-2.4 (-5.0 to 12.0)	2.0 (-4.4 to 6.0)	0.039
Functional Well Being	-3.0 (-18.0 to 5.0)**	-2.0 (-16.0 to 6.0)*	0.380
Breast Cancer Subscale	-2.0 (-5.0 to 3.0)*	0.0 (-14.9 to 7.0)	0.142
FACT G	-12.0 (-41.0 to 11.0)**	-3.0 (-20.4 to 11.0)	0.036
FACT B	-15.4 (-44.0 to 10.0)**	-2.9 (-35.3 to 12.0)	0.045

*$p < 0.05$, ** $p < 0.01$ when compared with baseline values within the same group

Table 4.5 Changes in FACT B scores, 30 days post surgery

Differential Scores (Day 30 – Day 1)	Inpatient Group n=13	Day Patient Group n=13	p value
Physical Well Being	-1.0 (-5.0 to 1.5)*	-2.0 (-7.0 to 4.0)	1.000
Social Well Being	0.0 (-5.8 to 2.0)	0.0 (-6.3 to 2.0)	0.801
Emotional Well Being	1.0 (-3.0 to 7.0)	2.8 (-4.0 to 6.0)	0.579
Functional Well Being	0.0 (-8.0 to 5.0)	0.0 (-13.3 to 6.0)	0.650
Breast Cancer Subscale	-1.0(-6.0 to 6.0)	1.0 (-15.0 to 7.0)	0.341
FACT G	-2.5 (-13.3 to 9.0)	2.0 (-25.6 to 10.0)	0.505
FACT B	-2.5 (-16.3 to 10.7)	5.9 (-40.6 to 13.0)	0.397

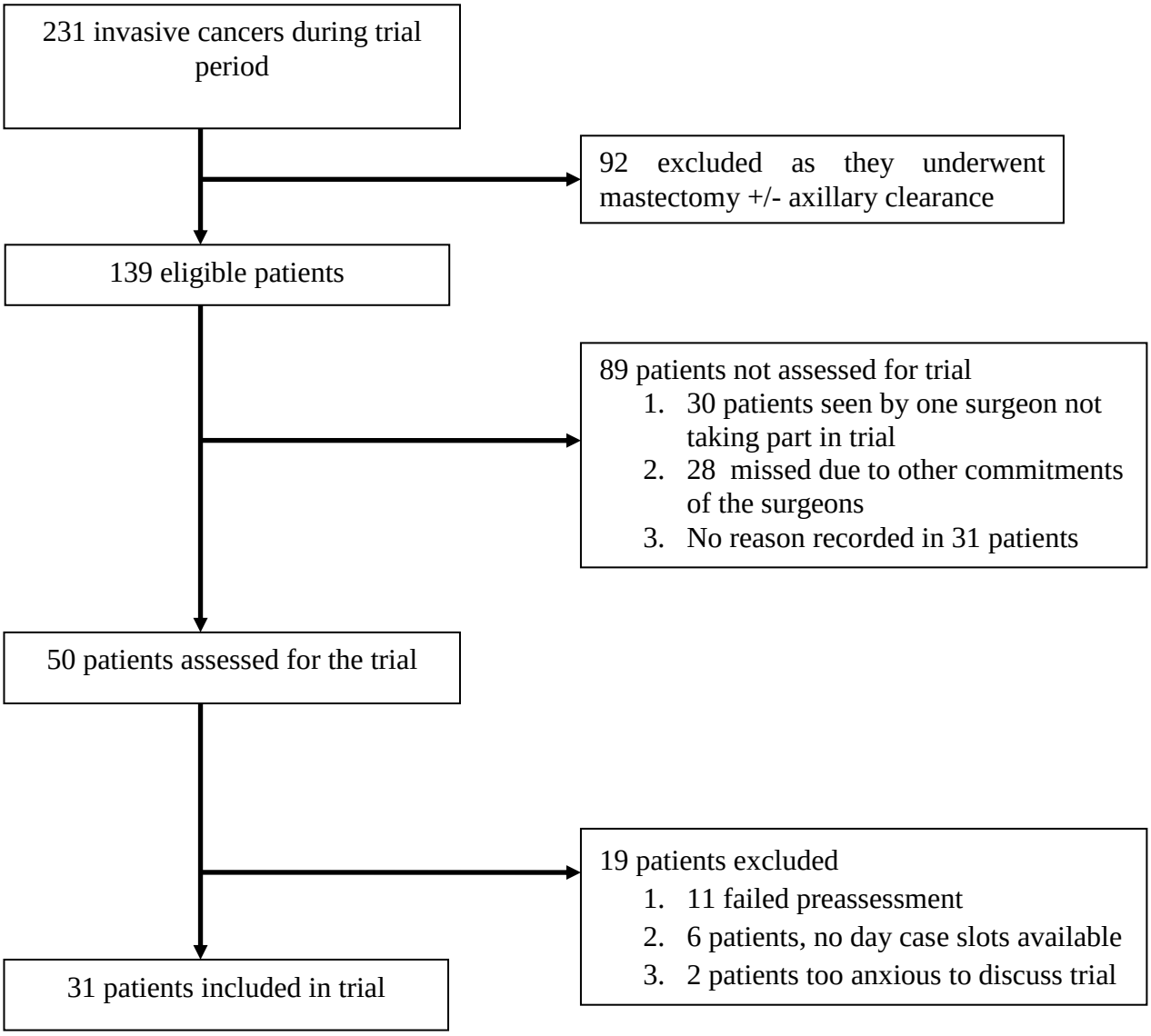

Figure 4.1: Details of all invasive breast cancers diagnosed during trial period.

5.0 Overall Conclusions

In this thesis, the feasibility, acceptability and safety of day surgery for breast cancer surgery have been investigated. At the outset, it was considered that day surgery for breast cancer was potentially a feasible option in the breast cancer patients in Glasgow. The evidence for this in literature was examined and the present practise in Glasgow was recorded and analysed to ascertain whether day surgery was feasible. A randomised controlled trial was then conducted to address the acceptability and safety of performing breast cancer surgery as day cases.

Day surgery may be a feasible alternative for breast cancer patients in Glasgow with nearly 50 percent of patients being potentially suitable for it.

The postoperative length of stay for breast cancer patients appeared to be mainly influenced by type of axillary procedure they undergo.

Postoperative length of stay did not appear to be affected by their age, which hospital they were operated at and the distance between the patient's residence and the hospital.

The planning for inpatient beds for breast cancer patients should take into account the proportion of symptomatic cancers being treated and the reoperations being performed.

There is evidence from literature and the pilot randomised controlled trial performed that compared to inpatients, day surgery patients have equivalent physical outcomes and better quality of life outcomes after their surgery.

6.0 Further Research

The suitability of patients who were discharged within a day of their surgery for true day surgery needs to be assessed further. It is not clear how many of these patients would be able to go home within four hours of their operation and how many would need to stay in overnight. Present preassessment criteria only pass patients if they are fit for true day surgery. Further criteria need to be developed for 23-hour care. Factors which may influence a patient's decision to stay overnight include their home circumstances such as whether they would be looked after by a responsible adult and their willingness to go home with a drain in situ. In the randomised controlled trial, only two out of the 50 patients failed preassessment for social reasons.

Another area which needs further research is the role of day surgery in the older patient. The breast cancer population is an aging population and one argument put forward is that day surgery may not be for the older patients. However, it has been noted in a study that postoperative cognitive dysfunction in elderly patients is less in day surgery patients compared to inpatients.[137] This is an area which can be researched in a randomised controlled trial with cognitive function measure as one of the outcomes.

Over the time that this research was conducted, two new day hospitals have been built in Glasgow. One in the North and the other in the South of Glasgow and the first patients were operated in June 2009. Day surgery for breast cancer has been carried out in both hospitals in a small selected group of patients and this has gone well. There is probably no possibility now to continue a randomised trial of day surgery as we are being encouraged to develop day surgery. However, we should continue to audit our practise in the day surgery setting looking at various outcomes.

6.1 Tools for Audit

Based on the results of this thesis and an in-depth study of the literature, I would like to propose that the following few measures may be developed into an audit tool to assess the quality of a day surgery service for breast cancer. Validated questionnaires should be used where possible.

1. Type of surgery and mode of presentation:
    i) Proportion of patients having BCS
    ii) Proportion of BCS patients having day surgery (with details of screen detected and symptomatic cancers)
2. Information and support provided
    i) Meetings with Breast Care Nurse. When and where.
    ii) Information provided to patients
    iii) Education tools used, if any.
3. Preassessment and Discharge criteria
    i) Preassessment criteria for 23-hour care if any
    ii) Any early discharge protocol for inpatients
    iii) Can patients go home with drain in situ? If yes, then who do they contact in case of a problem?
    iv) Physiotherapy advice given
4. Morbidity, readmission due to morbidity and mortality rates
5. Reoperation rates
6. Number of trips to hospital, both before and after surgery
7. Return to daily activity as measured using a patient diary and postoperative functional level at Day 7
8. Patient satisfaction surveys

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Appendices

Appendix 2.1 Search Strategy for Systematic Review

Databases Searched a.m. Friday 19th September 2008:

Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1950 to September Week 4 2008

British Nursing Index 1985 to September 2008

Cumulative Index to Nursing & Allied Health Literature (CINAHL) 1982 to September Week 3 2008

EMBASE 1980 to 2008 Week 38

PsycINFO 1967 to September Week 3 2008
The Cochrane Library

Search strategy summary

Keywords:
(breast cancer$ or breast neoplasm$ or breast tumor$ or breast tumour$ or Breast Adenocarcinoma$ or Breast Carcinoma$ or Breast Sarcoma$ or Cystosarcoma Phylloides or Intraductal Carcinoma$ or Phyllodes Tumor or Paget Nipple Disease or breast surgery or breast conser$ or axillary surgery or breast cancer axillary surgery or breast conservation surgery or breast biops$ or lymph node excision$ or sentinel lymph node biops$ or lymphadenectom$ or lymph node dissection$ or Breast Lesion$) or
or axillary surgery or axillary sampling or (conservative surgery and breast))

(day surgery or day case$ or ambulatory surgery or out patient$)

(double blind or meta analysis or randomi?ed or systematic review$ or random allocation)

Subject Headings:

exp mastectomy/
exp breast cancer/
exp breast neoplasms/
breast biopsy/
lymph node excision/ or sentinel lymph node biopsy/
exp breast surgery/ and exp cancer surgery/
lymphadenectomy/ or lymph node dissection/
“Breast Lesion"/
axillary lymph node/ or sentinel lymph node/
and
Ambulatory Surgical Procedures/
Ambulatory Surgery/

Medline and Embase Subject Headings that do not explode:

Ambulatory Surgical procedures
Ambulatory Surgery

Breast Biopsy
Lymph Node Dissection
Breast Lesion
Breast Biopsy

Limits:
Human/Humans
Publication types:
controlled clinical trial or guideline or meta analysis or practice guideline or randomized controlled trial [Publication type limit is not valid in: British Nursing Index,CINAHL,EMBASE, PsycINFO; records were retained]

Exclusions:
Animal$ or monkey$

The following were excluded to eliminate false drops identified by the extended keyword search:
Skin Neoplasms/
Melanoma/
Urogenital Surgical Procedures/
Urogenital Neoplasms/

Search strategy:

1. exp mastectomy/
2. exp breast cancer/
3. exp breast neoplasms/
4. breast biopsy/
5. lymph node excision/ or sentinel lymph node biopsy/
6. exp breast surgery/ and exp cancer surgery/
7. lymphadenectomy/ or lymph node dissection/
8. "Breast Lesion"/
9. axillary lymph node/ or sentinel lymph node/
10. (breast cancer$ or breast neoplasm$ or breast tumor$ or breast tumour$ or breast adenocarcinoma$ or beast carcinoma$ or breast sarcoma$ or cystosarcoma pylloides or intraductal carcinoma$ or phyllodes tumor or paget nipple disease or breast surgery or breast conser$ or axillary surgery or breast cancer axillary surgery or breast conservation surgery or breast biops$ or lymph node excision$ or sentinel lymph node biops$ or lymphadenectom$ or lymph node dissection$ or breast Lesion$).mp. [mp=ti, ab, hw, tc, id, it, ot, nm, sh, tn, dm, mf]
11. (conservative surgery and breast).mp. [mp=ti, ab, hw, tc, id, it, ot, nm, sh, tn, dm, mf]
12. (axillary surgery or axillary sampling).mp. [mp=ti, ab, hw, tc, id, it, ot, nm, sh, tn, dm, mf]
13. (day surgery or day case$ or ambulatory surgery or out patient$).mp. [mp=ti, ab, hw, tc, id, it, ot, nm, sh, tn, dm, mf]
14. "Ambulatory Surgical Procedures"/
15. "Ambulatory Surgery"/
16. or/1-12
17. or/13-15
18. 16 and 17
19. limit 18 to human
20. "Urogenital Surgical Procedures"/
21. "Melanoma"/
22. "Skin Neoplasms"/
23. "Urogenital Neoplasms"/
24. 19 not (or/20-23)

25. limit 24 to (controlled clinical trial or guideline or meta analysis or practice guideline or randomized controlled trial)
26. (double blind or meta analysis or randomi?ed or systematic review$ or random allocation).mp. [mp=ti, ab, hw, tc, id, it, ot, nm, sh, tn, dm, mf]
27. 24 and 26
28. 25 or 27
29. 24 not 28
30. remove duplicates from 28
31. remove duplicates from 29
32. 30 or 31
33. remove duplicates from 32

Cochrane Library search strategy

#1 (breast cancer* or breast tumor* or breast tumour* or breast surgery or breast conserv* or axillary surgery or breast conservation):ti,ab,kw

#2 (day surgery or day case* or ambulatory surg*):ti,ab,kw

#3 (#1 and #2)

#4 (double blind or randomised or randomized or meta analysis or meta-analysis):ti,ab,kw

#5 (#3 and #4)

#6 MeSH descriptor Ambulatory Surgical Procedures explode all trees

#7 (#5 and #6)

Cochrane Systematic Reviews were not relevant.

From #3 references to 1 Technology Assessment and 4 Economic Evaluations were saved.

Clinical Trials were not relevant in #3, even when keywords for study types were added in #5, hence MeSH heading added to contextualise in #7. All 16 references were on anaesthetics.

Appendix 4.1 Preassessment Criteria

Patients failed day surgery preassessment if:

- BMI > 35
- Patient unable to arrange a responsible adult escort
- Patient unable to arrange a responsible adult carer at home for the first 24 hours
- Patient unhappy to be a day patient
- MI within last 1 year
- BP systolic > 170 mmHg, diastolic > 110 mmHg
- Breathlessness on lying flat or waking at night "gasping for breath"
- Asthma, wheeze or breathlessness: Shortness of breath on walking; Currently taking oral steroids or has done so within last 3 months; Admitted to hospital with an exacerbation of asthma within last 3 months
- Seizures within last 6 months
- Suffered from stroke or mini stroke (TIA) within last year
- Suffers from a diagnosed bleeding problem
- Severe renal disease with deranged urea and electrolytes
- Anaesthetic problems: Patient or relative suffers from malignant hyperthermia
- IV drug abusers if currently injecting
- Patients drinking on an average 10 units or more of alcohol per day

Appendix 4.2 Patient Information Sheet

Victoria Infirmary
Participant Information Sheet

NHS Greater Glasgow and Clyde

Clinical trial comparing day care and in-patient care for breast cancer

What does this mean?
This is a trial comparing day care with in-patient care to find out which method of treatment is of most benefit to patients with breast cancer.

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?
Over the past 10 years, breast cancer treatments have changed and often less surgery is needed. In your case we only need to remove a part of your breast and will also need to take 4 glands from under the arm.
At the moment patients having your operation are admitted the day before surgery and discharged either in the evening after their surgery or the next day. For many years our patients with pre-cancer have had their surgery as day patients with no problems. The operation to the breast that these women have is exactly the same as your operation. The only difference being that you also need glands removed from under your arm.

The aim of the study is to find out which method of treatment is better for our patients. We would be comparing things like - wound infection rates, patient anxiety and satisfaction levels and recovery after the surgery.
Each patient would be followed up for a period of a month after their operation.

1 Why have I been chosen?
All patients who are to undergo breast-conserving surgery with axillary sampling at the Victoria Infirmary would be possible candidates for the study. Patients who fall into this group would undergo an assessment at the Day Surgery Unit at the Victoria Infirmary. Only those people who are found to be fit for day surgery would be asked to join the trial.

2 Do I have to take part?
It is up to you to decide whether or not take part. If you decide to take part you would be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving any reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

3 What will happen to me if I take part?
Sometimes because we do not know which way of treating is best, we need to make comparisons. People are put into groups and compared.

If you consent for the trial, one of the doctors would open a sealed envelope, which would say whether the operation should be carried with in-patient care or day care. The chance of being part of one or the other group is 50-50. What happens after that depends on which group you are in and is shown in the chart on the next page.

4 What do I have to do?
For the study it is very important that you fill in the diary provided to you everyday for 10 days and bring it with you when you come to the results clinic after your operation. You will be asked to complete a separate questionnaire. This should take no more than 10 minutes of your time.
You would also be given a further questionnaire to be filled 30 days after your operation. This would have to be posted back to us in a stamped, addressed envelope provided to you.

5 What are the possible disadvantages and risks of taking part?
No disadvantages are anticipated when taking part in the study, as you would undergo the same operation in both circumstances. It is important to know which method is better for you and hopefully the study would give us that answer.

6 What are the possible benefits?
Studies in other countries have shown day surgery to be beneficial for the patient. We are trying to find out what is best for patients in our community.

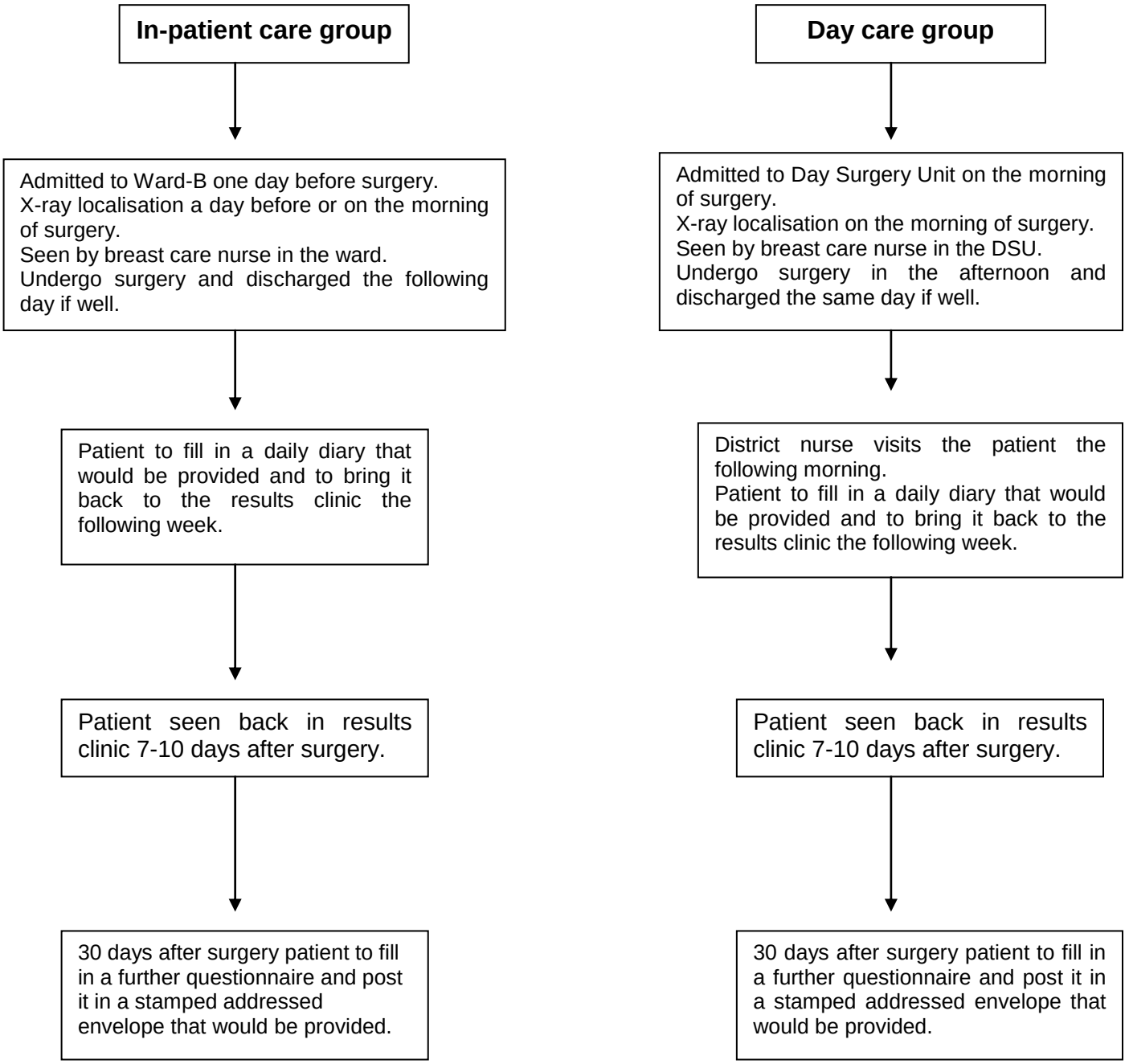
7 What if something goes wrong?
There is a small chance that patients in the day care group may require overnight admission to a ward in the hospital if they are not ready to go home for any reason.

8 Will my taking part in this trial be kept confidential?
All information that is collected about you during the course of the research will be kept strictly confidential. Any information about you that leaves the hospital will have your name and address removed so that you cannot be recognised from it.
Your GP would be notified about your participation in the trial.

9 What will happen to the results of the research study?
The results of the study would help in the planning of treatment for future patients. The results would be presented at national and international meetings and would be published in medical journals. You will not be identified in any report or presentation.

10 Who is funding this study?
There is no extra funding required for this study.

11 Who has reviewed the study?
The Research Ethics Committee
The Breast Team at the Victoria Infirmary
Outline of what happens after you are allocated to a group.



The important thing to remember is that the surgery being performed in both the groups would be the same. The difference would be in the type of care i.e. in-patient care or day care. All precautions would be taken to make sure that the best care is provided.

Emergency contact numbers- Surgical SHO: 0141 2016000 Page: 5021
For further information about trial-

Mr. Sekhar Marla (Research Fellow): 0141 2115440

We would like to thank you for taking part in this study.

Appendix 4.3 Consent Form for Trial

Victoria Infirmary Consent Form

NHS Greater Glasgow and Clyde

Project Title: A pilot randomised clinical trial of day surgery for breast cancer

Patient name: _____ Date of Birth: _____

To be completed by the patient

	Please Initial	
	Yes	**No**
Have you read the Participant Information Sheet (Version1.1/ Dated 08/02/07)?		
Have you had the opportunity to ask questions and to discuss the study?		
Have you received satisfactory answers to all of your questions?		
Have you received enough information about the study?		
Do you agree to let your GP be informed about your participation in the trial?		

Do you understand that you are free to withdraw from the study:

	Please Initial	
	Yes	**No**
At any time?		
Without having to give a reason?		
Without affecting your future medical care?		
Do you agree to take part in this study?		

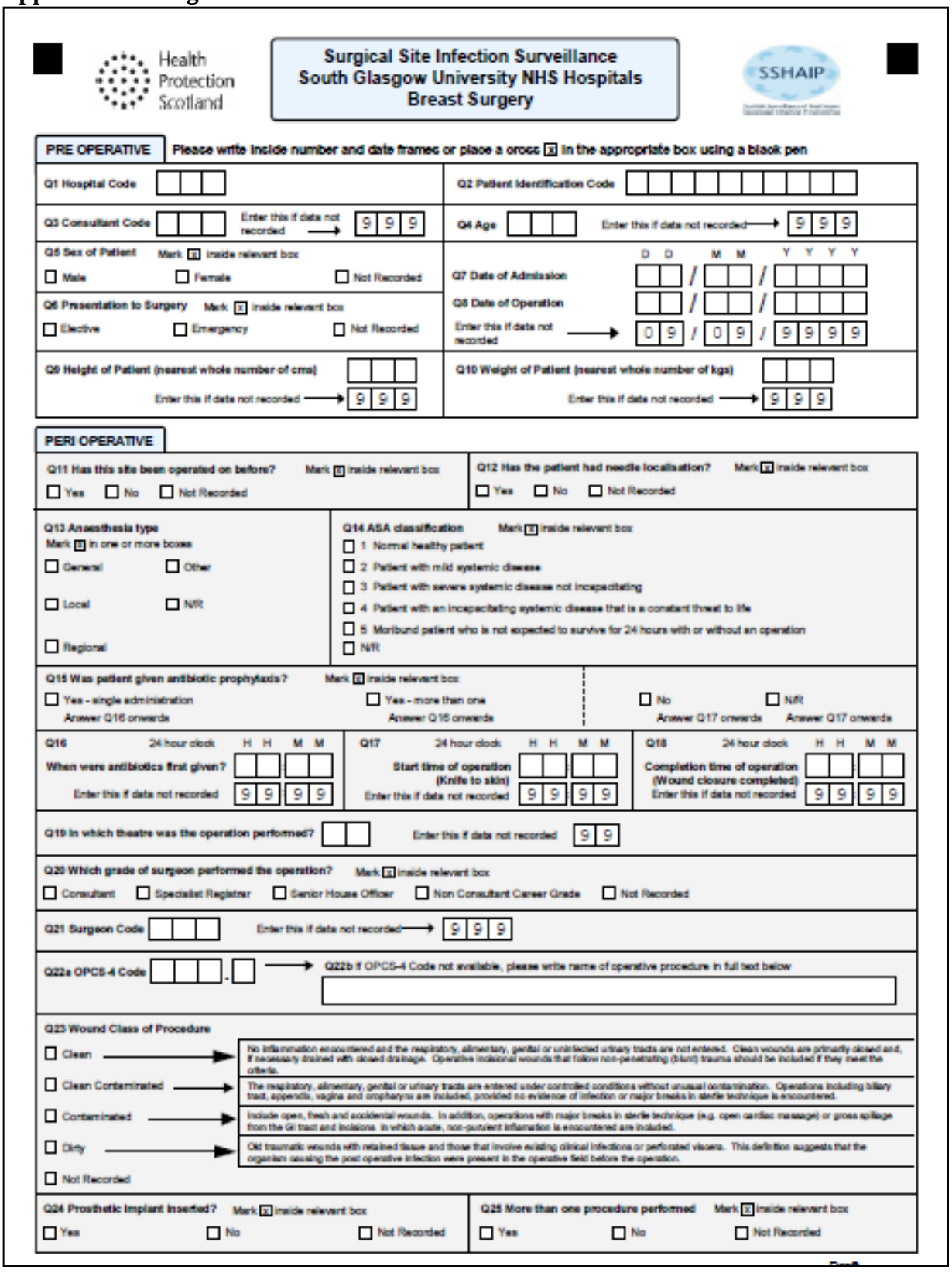
Signed _____ Date _____

Name in block letters _____

Signature of witness _____ Date _____

Name in block letters _____

Appendix 4.4 Surgical Site Infection Form



Health Protection Scotland

Surgical Site Infection Surveillance
South Glasgow University NHS Hospitals
Breast Surgery

SSHAIP

PRE OPERATIVE Please write in/circle number and date frames or place a cross [x] in the appropriate box using a black pen

Q1 Hospital Code [ ][ ][ ]

Q2 Patient Identification Code [ ][ ][ ][ ][ ][ ][ ][ ][ ][ ]

Q3 Consultant Code [ ][ ][ ] Enter this if data not recorded → [9][9][9]

Q4 Age [ ][ ][ ] Enter this if data not recorded → [9][9][9]

Q5 Sex of Patient Mark [x] inside relevant box
☐ Male ☐ Female ☐ Not Recorded

Q6 Presentation to Surgery Mark [x] inside relevant box
☐ Elective ☐ Emergency ☐ Not Recorded

Q7 Date of Admission [D D] / [M M] / [Y Y Y Y]

Q8 Date of Operation [D D] / [M M] / [Y Y Y Y]

Enter this if data not recorded → [0][9] / [0][9] / [9][9][9][9]

Q9 Height of Patient (nearest whole number of cms) [ ][ ][ ]
Enter this if data not recorded → [9][9][9]

Q10 Weight of Patient (nearest whole number of kgs) [ ][ ][ ]
Enter this if data not recorded → [9][9][9]

PERI OPERATIVE

Q11 Has this site been operated on before? Mark [x] inside relevant box
☐ Yes ☐ No ☐ Not Recorded

Q12 Has the patient had needle localisation? Mark [x] inside relevant box
☐ Yes ☐ No ☐ Not Recorded

Q13 Anaesthesia type
Mark [x] in one or more boxes
☐ General ☐ Other
☐ Local ☐ N/R
☐ Regional

Q14 ASA classification Mark [x] inside relevant box
☐ 1 Normal healthy patient
☐ 2 Patient with mild systemic disease
☐ 3 Patient with severe systemic disease not incapacitating
☐ 4 Patient with an incapacitating systemic disease that is a constant threat to life
☐ 5 Moribund patient who is not expected to survive for 24 hours with or without an operation
☐ N/R

Q15 Was patient given antibiotic prophylaxis? Mark [x] inside relevant box
☐ Yes - single administration — Answer Q16 onwards
☐ Yes - more than one — Answer Q16 onwards
☐ No — Answer Q17 onwards
☐ N/R — Answer Q17 onwards

Q16 24 hour clock H H M M
When were antibiotics first given? [ ][ ] : [ ][ ]
Enter this if data not recorded [9][9] : [9][9]

Q17 24 hour clock H H M M
Start time of operation (Knife to skin) [ ][ ] : [ ][ ]
Enter this if data not recorded [9][9] : [9][9]

Q18 24 hour clock H H M M
Completion time of operation (Wound closure completed) [ ][ ] : [ ][ ]
Enter this if data not recorded [9][9] : [9][9]

Q19 In which theatre was the operation performed? [ ][ ] Enter this if data not recorded [9][9]

Q20 Which grade of surgeon performed the operation? Mark [x] inside relevant box
☐ Consultant ☐ Specialist Registrar ☐ Senior House Officer ☐ Non Consultant Career Grade ☐ Not Recorded

Q21 Surgeon Code [ ][ ][ ] Enter this if data not recorded → [9][9][9]

Q22a OPCS-4 Code [ ][ ][ ] . [ ] → Q22b If OPCS-4 Code not available, please write name of operative procedure in full text below

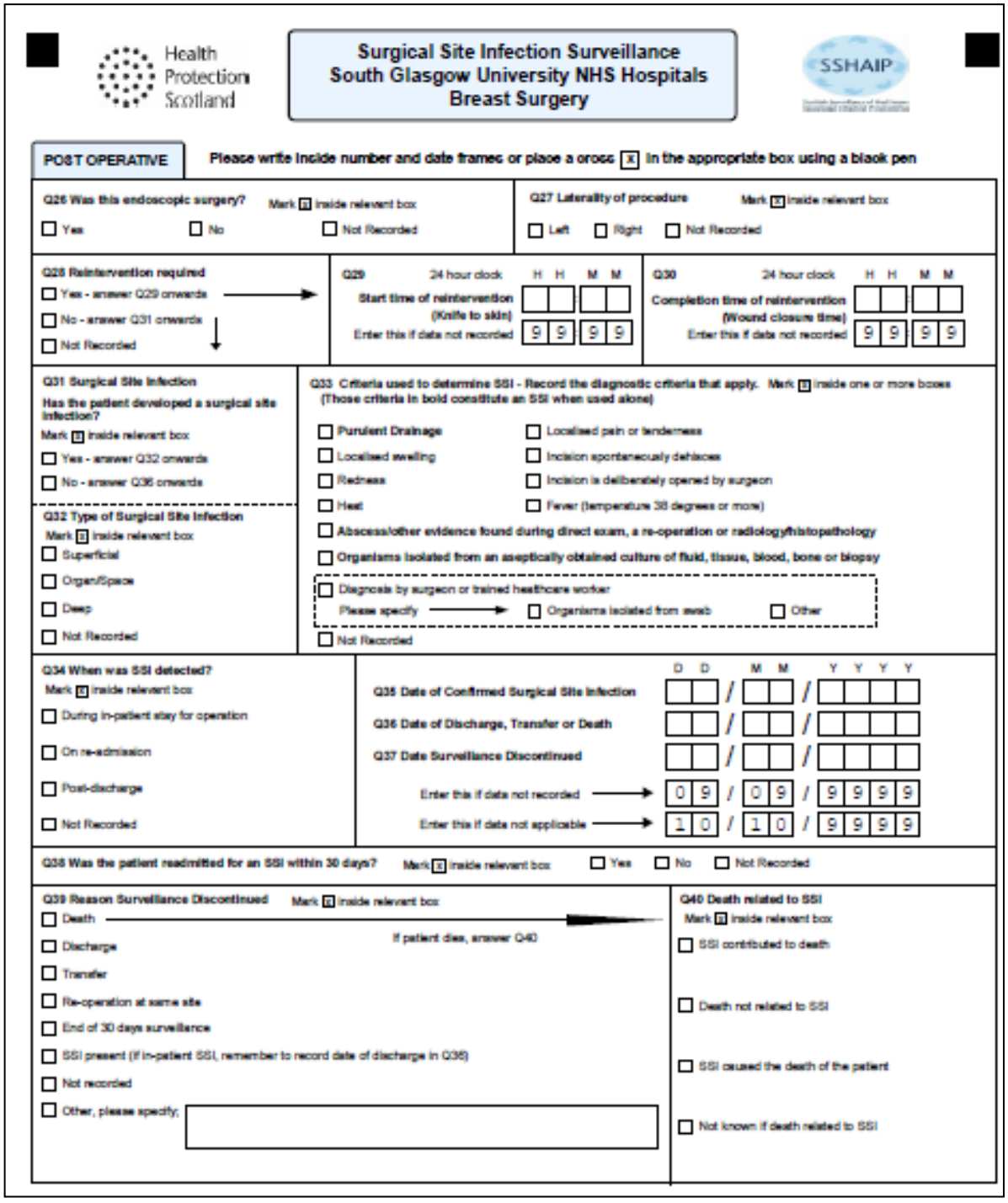
Q23 Wound Class of Procedure

☐ Clean →	No inflammation encountered and the respiratory, alimentary, genital or urinary tracts are not entered. Clean wounds are primarily closed and, if necessary drained with closed drainage. Operative incisional wounds that follow non-penetrating (blunt) trauma should be included if they meet the criteria.
☐ Clean Contaminated →	The respiratory, alimentary, genital or urinary tracts are entered under controlled conditions without unusual contamination. Operations including biliary tract, appendix, vagina and oropharynx are included, provided no evidence of infection or major breaks in sterile technique is encountered.
☐ Contaminated →	Include open, fresh and accidental wounds. In addition, operations with major breaks in sterile technique (e.g. open cardiac massage) or gross spillage from the GI tract and incisions in which acute, non-purulent inflammation is encountered are included.
☐ Dirty →	Old traumatic wounds with retained tissue and those that involve existing clinical infections or perforated viscera. This definition suggests that the organism causing the post operative infection were present in the operative field before the operation.

☐ Not Recorded

Q24 Prosthetic Implant Inserted? Mark [x] inside relevant box
☐ Yes ☐ No ☐ Not Recorded

Q25 More than one procedure performed Mark [x] inside relevant box
☐ Yes ☐ No ☐ Not Recorded



Health Protection Scotland

Surgical Site Infection Surveillance
South Glasgow University NHS Hospitals
Breast Surgery

SSHAIP

POST OPERATIVE — Please write inside number and date frames or place a cross [X] in the appropriate box using a black pen

Q26 Was this endoscopic surgery? Mark [X] inside relevant box
☐ Yes ☐ No ☐ Not Recorded

Q27 Laterality of procedure Mark [X] inside relevant box
☐ Left ☐ Right ☐ Not Recorded

Q28 Reintervention required
☐ Yes - answer Q29 onwards →
☐ No - answer Q31 onwards ↓
☐ Not Recorded

Q29 24 hour clock H H : M M
Start time of reintervention (Knife to skin)
Enter this if data not recorded: 9 9 : 9 9

Q30 24 hour clock H H : M M
Completion time of reintervention (Wound closure time)
Enter this if data not recorded: 9 9 : 9 9

Q31 Surgical Site Infection
Has the patient developed a surgical site infection?
Mark [X] inside relevant box
☐ Yes - answer Q32 onwards
☐ No - answer Q36 onwards

Q32 Type of Surgical Site Infection
Mark [X] inside relevant box
☐ Superficial
☐ Organ/Space
☐ Deep
☐ Not Recorded

Q33 Criteria used to determine SSI - Record the diagnostic criteria that apply. Mark [X] inside one or more boxes
(Those criteria in bold constitute an SSI when used alone)

☐ **Purulent Drainage**
☐ Localised swelling
☐ Redness
☐ Heat
☐ Localised pain or tenderness
☐ Incision spontaneously dehisces
☐ Incision is deliberately opened by surgeon
☐ Fever (temperature 38 degrees or more)
☐ **Abscess/other evidence found during direct exam, a re-operation or radiology/histopathology**
☐ **Organisms isolated from an aseptically obtained culture of fluid, tissue, blood, bone or biopsy**
☐ Diagnosis by surgeon or trained healthcare worker
Please specify → ☐ Organisms isolated from swab ☐ Other
☐ Not Recorded

Q34 When was SSI detected?
Mark [X] inside relevant box
☐ During in-patient stay for operation
☐ On re-admission
☐ Post-discharge
☐ Not Recorded

D D / M M / Y Y Y Y

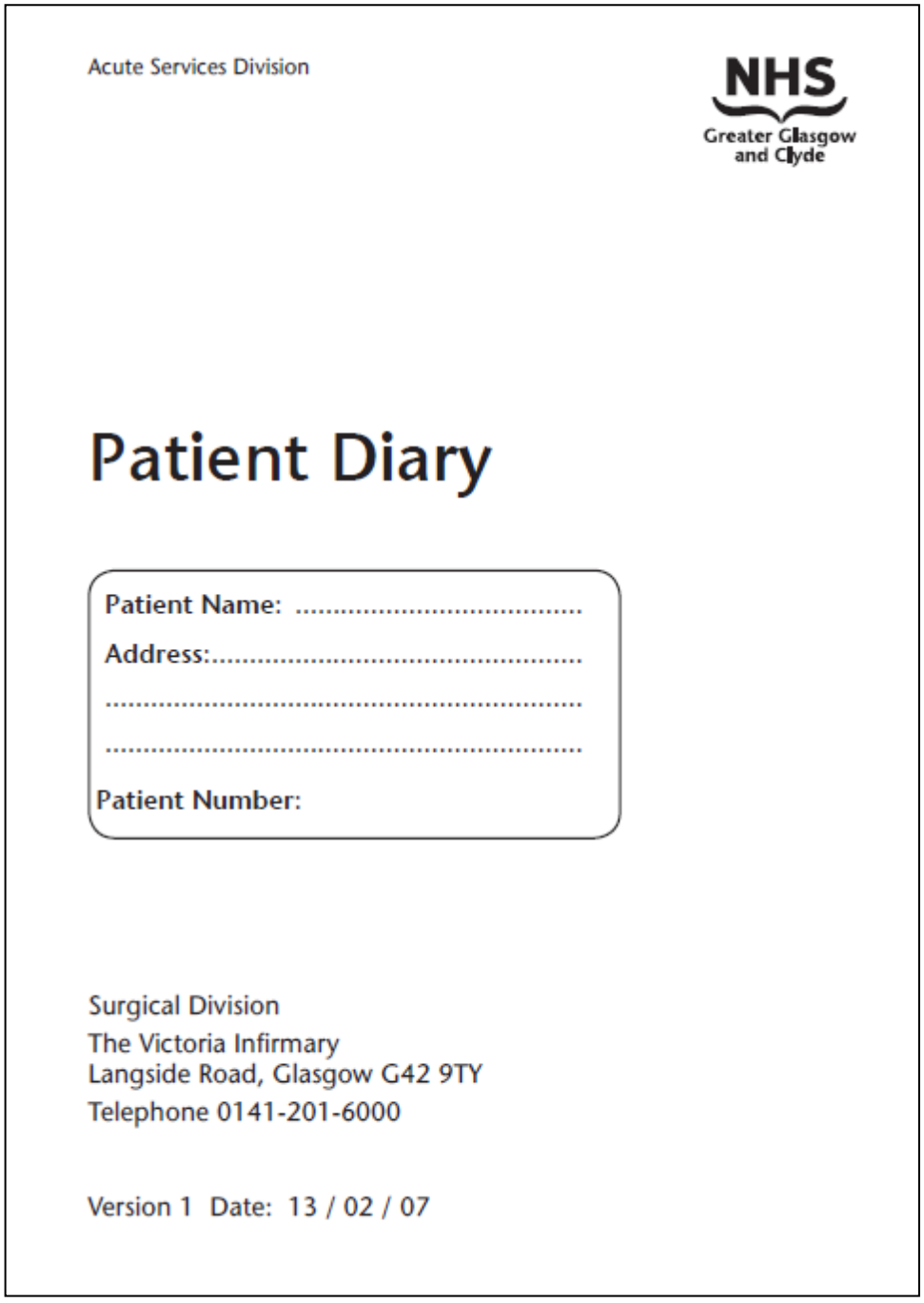
Q35 Date of Confirmed Surgical Site Infection / /
Q36 Date of Discharge, Transfer or Death / /
Q37 Date Surveillance Discontinued / /
Enter this if data not recorded → 0 9 / 0 9 / 9 9 9 9
Enter this if data not applicable → 1 0 / 1 0 / 9 9 9 9

Q38 Was the patient readmitted for an SSI within 30 days? Mark [X] inside relevant box ☐ Yes ☐ No ☐ Not Recorded

Q39 Reason Surveillance Discontinued Mark [X] inside relevant box
☐ Death → If patient dies, answer Q40
☐ Discharge
☐ Transfer
☐ Re-operation at same site
☐ End of 30 days surveillance
☐ SSI present (if in-patient SSI, remember to record date of discharge in Q36)
☐ Not recorded
☐ Other, please specify:

Q40 Death related to SSI
Mark [X] inside relevant box
☐ SSI contributed to death
☐ Death not related to SSI
☐ SSI caused the death of the patient
☐ Not known if death related to SSI

Appendix 4.5 Patient Diary



Acute Services Division

NHS
Greater Glasgow and Clyde

Patient Diary

Patient Name: .....

Address:.....

.....

.....

Patient Number:

Surgical Division
The Victoria Infirmary
Langside Road, Glasgow G42 9TY
Telephone 0141-201-6000

Version 1 Date: 13 / 02 / 07

Your Comments and Questions

Daily questions from Day 1 to Day 7

Day 1.

DAY	MON	TUE	WED	THUR	FRI	SAT	SUN

In the last 24 hours:

1. We would like you to indicate on this scale how good or bad your own health is today.

0 Worst Imaginable — Best Imaginable 10

2. Did you feel you got enough rest? Yes / No
   If no, please explain why?
   .....

3. On a scale of 0 – 10, how much pain did you have? Please mark.

0 No Pain — Worst Pain Imaginable 10

4. Did you take any pills for pain? Yes / No
   If yes, what?
   .....

5. On a scale of 0-10, how much nausea did you have?

0 No Nausea — Very Severe Nausea 10

6. Were you sick? Yes / No
7. Did you take any pills for pain or sickness today? Yes / No
   If yes, what?
   .....
8. Did you have any worries? Yes / No
   If yes, what?
   .....
9. Have you been out of the house? Yes / No
10. Did you need to phone anyone following your operation? Yes / No
    If yes, what was the reason?
    .....
    Who did you contact?
    .....
    What happened?
    .....
    .....

Final Questions

Final Questions

1. If you were to have the same operation again, would you have it done in the same way (Inpatient / day patient)? Yes / No
2. Would you recommend this type of care (Inpatient / day care) to a friend?
   Yes / No
3. If you needed any help now, who would be the first person, you would contact?
   .....
4. Were you given information about:
   - Your cancer treatment Yes / No
     If you wish please comment:.....
     .....
   - Discharge advice: Yes / No
     If you wish please comment: .....
     .....
   - Arm and shoulder exercises: Yes / No
     If you wish please comment: .....
     .....

Thank you for completing the diary

Please remember to bring your diary with you when you come to the Results Clinic.

Appendix 4.6 FACT B Questionnaire Baseline, Day 7 and Day 30

Acute Services Division

FACT B (Version 4) Form
February 2007

Patient Number:

NHS Greater Glasgow and Clyde

Baseline

Below is a list of statements that other people with your illness have said are important. By **circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.**

	PHYSICAL WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
GP1	I have a lack of energy	0	1	2	3	4
GP2	I have nausea	0	1	2	3	4
GP3	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
GP4	I have pain	0	1	2	3	4
GP5	I am bothered by side effects of treatment	0	1	2	3	4
GP6	I feel ill	0	1	2	3	4
GP7	I am forced to spend time in bed	0	1	2	3	4

	SOCIAL/FAMILY WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
GS1	I feel close to my friends	0	1	2	3	4
GS2	I get emotional support from my family	0	1	2	3	4
GS3	I get support from my friends	0	1	2	3	4
GS4	My family has accepted my illness	0	1	2	3	4
GS5	I am satisfied with family communication about my illness	0	1	2	3	4
GS6	I feel close to my partner (or the person who is my main support)	0	1	2	3	4
Q1	*Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please check this box* ☐ *and go to the next section.*					
	I am satisfied with my sex life	0	1	2	3	4

By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

	EMOTIONAL WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
GE1	I feel sad	0	1	2	3	4
GE2	I am satisfied with how I am coping with my illness	0	1	2	3	4
GE3	I am losing hope in the fight against my illness	0	1	2	3	4
GE4	I feel nervous	0	1	2	3	4
GE5	I worry about dying	0	1	2	3	4
GE6	I worry that my condition will get worse	0	1	2	3	4

	FUNCTIONAL WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
GF1	I am able to work (include work at home)	0	1	2	3	4
GF2	My work (include work at home) is fulfilling	0	1	2	3	4
GF3	I am able to enjoy life	0	1	2	3	4
GF4	I have accepted my illness	0	1	2	3	4
GF5	I am sleeping well	0	1	2	3	4
GF6	I am enjoying the things I usually do for fun	0	1	2	3	4
GF7	I am content with the quality of my life right now	0	1	2	3	4

By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

	ADDITIONAL CONCERNS	Not at all	A little bit	Some-what	Quite a bit	Very much
B1	I have been short of breath	0	1	2	3	4
B2	I am self-conscious about the way I dress	0	1	2	3	4
B3	One or both of my arms are swollen or tender	0	1	2	3	4
B4	I feel sexually attractive	0	1	2	3	4
B5	I am bothered by hair loss	0	1	2	3	4
B6	I worry that other members of my family might someday get the same illness I have	0	1	2	3	4
B7	I worry about the effect of stress on my illness	0	1	2	3	4
B8	I am bothered by a change in weight	0	1	2	3	4
B9	I am able to feel like a woman	0	1	2	3	4
P2	I have certain parts of my body where I experience significant pain	0	1	2	3	4