**Abstract**

*Introduction*

Older breast cancer patients are less likely to have surgery; in part due to co-morbidities and reduced functional ability. However, there is little consensus on how best to assess surgical risk for this patient group.

*Methods*

We investigated the ability of pre-treatment health measures to predict complications in a prospective, cohort study of a consecutive series of 664 women aged ≥70 years undergoing surgery for operable (stage 1-3a) breast cancer at 22 English breast units (2010-2013). Data on treatment, surgical complications, health measures and tumour characteristics were collected by case note review and/or patient interview. Outcome measures: All complications and serious complications within 30days of surgery.

*Results*

41% experienced ≥1 complications, predominantly seroma or primary/minor infections. 6.5% had serious complications. More extensive surgery predicted a higher number of complications but not serious complications. Older age did not predict complications. Several health measures were associated with complications univariately and included in multivariable analyses, adjusting for type/extent of surgery and tumour characteristics. In the final models pain predicted a higher count of complications (OR 1.006, 95% CI:1.002-1.011). Fatigue (IRR 1.019, 95% CI:1.006-1.033), low platelets (OR 4.189, 95% CI:1.025-17.123) and pulse rate (OR 0.957, 95% CI:0.926-0.990) predicted serious complications.

*Conclusion*

Predictors of surgical risk were identified in multivariable models, but effects were weak with 95% confidence intervals close to unity. The search for more robust predictors continues. However, risk of serious complications is low. In line with national guidance, older women should be given the same consideration for breast cancer surgery as younger patients.

## Introduction

Breast cancer is predominantly a disease of old age: incidence doubles from 215 per 100,000 for women aged 45–49 to 442 per 100,000 for those aged ≥85 years (England 2011). One third of all new cases in England are diagnosed in women aged ≥70 years[1]. Within an ageing population, both the number and proportion of older patients requiring treatment at breast units is rising and set to continue to do so for the next 50 years[2].

Primary surgery (mastectomy or wide local excision of the tumour) is the recommended initial treatment for early stage breast cancer[3;4]. However, the percentage of women having surgery for breast cancer in England decreases with older age; from as low as 40% of patients aged ≥80 years to around 90% of younger age groups[5;6].

UK treatment guidelines state that 'significant co-morbidity' may preclude surgery for patients with early stage breast cancer[3;4]. As co-morbidity increases with older age this may account for the lower surgical rates amongst elderly patients. However, although co-morbidity does explain some of the decline in surgical rates with age, older women are still less likely to have surgery once co-morbidity is adjusted for[5]. Our recent study suggests that adjusting for wider measures of health, such as functional decline/frailty, may explain lack of breast surgery for older women up to, but not beyond, the age of 85 years[7]; providing evidence that, at least up to the age of 85 years, patient health is the primary consideration when assessing surgical risk, rather than age.

However, there is little consensus on how best to assess surgical risk for older breast cancer patients. Precluded from earlier trials, the evidence base on older patients' risks and benefits of treatment is poor[8;9]. A more recent older age specific trial comparing surgery with endocrine therapy vs. endocrine therapy alone for patients aged ≥70 years closed due to slow recruitment[9]. Patients largely opted not to take part in this trial in which they had a 50% chance of not having surgery; possibly because surgery is now such an accepted mainstay of treatment for early stage breast cancer. In this context cohort studies can help bridge the knowledge gap by identifying pre-treatment health measures which predict surgical complications.

One such large cohort investigating surgical risk assessment, for all ages/types of surgery, combines measures used within pre-operative assessment such as co-morbidity and body mass index into predictive models. The US-based National Surgical Quality Improvement Program (NSQIP) has developed a universal measure of surgical risk based on all surgical procedures at 393 enrolled hospitals[10]. Multivariate models of mortality and morbidity are based on 21 pre-operative measures recorded on the dataset. Model discrimination is good (AUC >0.8) presenting a considerable step forward in risk stratification for surgical patients in general. Limitations of this risk tool include restriction to pre-operative measures recorded on the dataset and lack of disease and procedure specific pre-operative measures such as type/extent of surgery[11]. Underestimation of complications rates in the NSQIP dataset has also been reported due to non-inclusion of procedure specific complications and limitation to academic hospitals enrolled in this quality improvement programme; which have better surgical outcomes compared to the rest of the US[11;12]. Generalisability to the UK is also questionable given the difference in health care systems. The lack of a British version of NSQIP is likely to increase interest in risk stratification in the UK[12].

Surgical risk assessment specifically for older cancer patients has been developed to also incorporate measures of functional decline/frailty. The Comprehensive Geriatric Assessment (CGA) is a battery of varying health status and functional tests recommended by the International Society for Geriatric Oncology as essential to treatment decision making with older cancer patients. However, there is a lack of consensus on which health measures best predict risk and therefore should be included in a CGA[13]. Functional status and fatigue have been found to predicted surgical complications amongst generic cancer patients[14]. However, as risk varies considerably for different types of surgery there is a need to identify health measures which predict surgical risk within specific cancer groups[15].

As part of a wider research programme we undertook a prospective, cohort study investigating the extent to which the lack of surgery for older breast cancer patients is explained by patient choice or poor health[7]. Here we report on the study's secondary aim of investigating the ability of a range of pre-treatment health measures to predict 30 day surgical complications amongst a subset of 664 patients aged ≥70 years who received surgery.

## Methods

*Study design*

This is a prospective, cohort study of a consecutive series of women aged ≥70 years undergoing surgery for operable (stage 1-3a) breast cancer at 22 breast units, predominantly in Northwest England, over a period of 33 months (2010-2013). Data on treatment, surgical complications, a range of pre-operative health measures and tumour characteristics were collected by case note review and/or patient interview[7].

*Primary outcome measure:* Complications within 30 days of primary surgery (mastectomy or Wide Local Excision, WLE) for operable (stage 1-3a) breast cancer. All patients were followed up for 90 days post diagnosis. Patients not having primary surgery within 90 days of diagnosis were not included in this study. As initial WLE may be followed by mastectomy, patients were classified as receiving mastectomy or WLE based on the most extensive primary surgery. Similarly axillary node procedure was based on the most extensive dissection. Two measures of complications are used: a count of all complications and having serious complications (vs. not). All complications occurring within 30 days of the last primary surgery were recorded; non infections based on a checklist developed from the East Anglian Hip Fracture Audit[16] and the Pre-operative Assessment of Cancer in the Elderly Project[14], with breast surgery specific items[17;18] and infectious complications based on the national prevalence survey of hospital acquired infections[19]. Complications occurring after the commencement of adjuvant radiotherapy or chemotherapy were not included. Patients were classified as having serious complications if they had complications (other than a seroma or primary/minor infection) which warranted readmission as an inpatient, delayed discharge or other procedure. Delayed discharge was defined by being in excess of median length of stay[20] and the maximum time limits reported as 'usual' in national NHS patient information sources[21] i.e. more than one day for WLE and five or more days for mastectomy. Other procedures included as indicating a serious complication were return to theatre, treatment for confirmed hospital acquired MRSA infection, stroke or pulmonary embolism, extensive wound repair (i.e. excising of necrotic tissue/ applying sutures/wound packing) and blood transfusions.

*Explanatory variables*: Age, measures of health, tumour characteristics, demographics and hospital resources.

*Measures of health:* A range of health measures were recorded both from self-report at a patient interview (undertaken within 2 weeks of diagnosis and before surgery) or from pre-operative assessment as recorded in the case notes. Measures included are listed in Box 1, and represent patients' functional/health status and Health Related Quality of Life (HRQoL), in addition to co-morbidity and other clinical measures recorded at the pre-operative health assessment. Self-report measures were primarily selected based on ease of administration, validity, reliability, acceptability to older people[22;23], and prediction of treatment received[24;25] and/or treatment outcomes[13-15]. Clinical measures recorded at pre-operative assessment were also considered if data were available for at least 85% of sample. Classification for blood results was based on the National Pathology Harmonisation Standardisation project[26;27].

*Tumour characteristics*: Pre-treatment assessments of tumour characteristics, tumour size, stage, nodal and steroid receptor status were recorded based on clinical, imaging and fine needle/core biopsy assessments (cTNM[28]).

*Socio–demographics*: Socio-economic class is measured using the Office of National Statistics Socio-Economic Classification[29] and based on main occupation pre-retirement if retired and the highest classification if the participant was married or living with a partner. Ethnicity was recorded based on UK census classification categories[30]. Of the 22 breast units in the study 19 were in the North West of England, two in London and one in the Midlands.

*Inclusion criteria*

*Women:* Men were not included as <1% of all invasive breast cancer occurs in men[1] and surgical management may differ[3;4].

*Aged ≥70 years*: Women aged 70-74 years are included as a reference group.

*Having primary surgery within 90 days of diagnosis of a new episode of operable invasive breast cancer (stage 1-3a)*: Carcinoma in situ, stage 3b, metastatic and recurrent breast cancers are not included as the standards for operable breast cancer do not apply[3;4].

*Screening/Accrual*

Screening and accrual processes are reported elsewhere[7]. Of the 800 patients aged ≥70 years, recruited into the main study investigating the extent to which patient health and choice explain lack of surgery, 664 (83%) had primary surgery within the follow up period of 90 days and therefore are included in the analyses of prediction of surgical complications reported here.

*Data Collection.*

Patients who agreed to take part were interviewed within 30 days of diagnosis, before surgery took place. The interview comprised demographic variables and measures of health detailed above. The case notes of each patient were reviewed up to 3 months post-diagnosis, using a proforma developed to collect data on tumour characteristics at diagnosis, treatments undertaken, co-morbidity and complications. Inter-rater agreement levels for the proforma items satisfied the Kappa >0.6 criterion indicating substantial to perfect agreement[31]. Three percent of case note review proformas and 8% of patient interviews were tested for data input errors. Error rates per data item inputted were <0.5% so no further data-checking was warranted. The proformas of patients having complications were initially assessed by AMS and KL independently against the above criteria for serious complications devised with NB and CT. Disagreements were resolved by consensus with any final outstanding decisions made by NB or CT.

*Analyses*

Explanatory variables were investigated in univariable analysis using Pearson's $\chi^2$ test, Fisher's exact test, $\chi^2$ test for trend and univariable regression analyses (two tailed with $\alpha = 0.05$). The distribution of continuous variables was assessed for Normality using the Shapiro–Wilk W test. Associations between non-Normal variables and categorical data were investigated using the non-parametric two sample Wilcoxon rank sum (Mann Whitney test) and Kruskal-Wallis equality-of-populations rank test. Associations for parametric variables were investigated using the two sample t-test. Due to the large number of health measures tested for univariate associations with complications, significance was considered after a Bonferroni adjustment for multiple testing was calculated.

Independent variables found to be significantly associated with outcomes in univariable analyses were used as independent variables in the subsequent multiple regressions (forward stepwise). Models were built in line with our Data Analysis Plan agreed *a priori* with the project's Independent Data Monitoring Committee modifying an approach suggested by Hosmer and Lemeshow (2000)[32]. Type of surgery (mastectomy vs. WLE) and extent of axillary node surgery formed the base models based on clinical relevance and previous literature[11;33]. Remaining variables were initially tested against the null model and retained based on (1) the difference between the model with the additional variable and the previous model using the Likelihood Ratio Test (a.k.a. analysis of deviance) or (2) producing a significant coefficient in the model (both at a 5% significance level). Explanatory variables were considered in three groups and added into the model in order of importance to the secondary aim of the study i.e. health measures, socio-demographics and then tumour characteristics. Within each group the order in which variables were added into the model was determined by minimising Bayesian Information Criterion (BIC) values of each variable added into the model individually. Those variables with lower BIC values were added in sequentially starting with the variable giving the lowest value. At each step an individual variable's contribution to the model was assessed using the above two criteria. In order to reduce the likelihood of multicollinearity, and ensure the number of cases in the model could sustain the potentially high number of health measures, they were only retained in the model if they produced both a significant coefficient and likelihood ratio test. Tumour characteristics and socio demographic variables were retained if they had a significant likelihood ratio test only.

Once each group of variables had been added VIFs (Variance Inflation Factors) were checked and variables exhibiting factors above 10 investigated to prevent multicolinearity[34]. Logistic regression models were tested for goodness of fit (Hosmer & Lemeshow) and discrimination (area under Receiver Operating Characteristic curve). Variables included in the final models were tested for two way interactions.

A sensitivity analysis was conducted by additionally performing backwards stepwise regression, and this approach led to comparable final models and therefore suggested robust results.

Data were analysed using STATA version 12.1[35].

*Sample size*

The sample size was determined *apriori* by the study's primary aim as reported elsewhere[7]. In order to test the study's aim reported in this paper, the recommended sample size is determined by the number of explanatory variables included in the multivariate models predicting the two complications outcome measures. However, the given sample size of 664 should also be sufficient to support negative binomial (predicting count of complications) as the sample size $\geq 50 + 8p$ and $\geq 104 + p$ (where p is the number of explanatory variables)[36]. Logistic regression (predicting serious complications) should have around 10 cases for each explanatory variable for both categories of the dependent variable[37;38], although in other scenarios it has been shown that 5 cases for each explanatory variable is sufficient[39]. In order to help meet this guidance health measures with non-significant coefficients (at 5% level) were dropped from the model once the total number of variables exceeded this limit during the model building process. In practice only one health measure was lost from the model for this reason and the resultant final logistic regression model included five explanatory variables (i.e. 8 events per variable).

**Results**

*Sample characteristics*

Six hundred and sixty four women were included, all of whom had primary surgery within 90 days of diagnosis. Half (49.5%, n = 329), had a mastectomy and half (50.5%, n = 335) Wide Local Excision (WLE); 39% were aged 70-74 years, 30% 75- 79 years, 19% 80-84 years and 12% aged ≥85 years (Table 1). The sample was predominantly of professional/ intermediate social class and white ethnic group. Over half were treated at a district general hospital rather than a university teaching hospital. Over 40% of the sample were recorded with stage I disease at diagnosis, 55.9% were stage II or IIIa hence regarded as having early operable breast cancer[40]. Over two thirds of the sample (70.3%) had no nodal involvement recorded at diagnosis and over half the sample had small tumours of ≤20mm (56.3%). The vast majority of participants were steroid receptor positive for either oestrogen or progesterone receptors (83.6%).

*Complications rates*

Of the 664 women in the sample, 41.0% (272) had some form of complication within 30 days of surgery (95% CI: 37.2-44.7%) (Figure 1). However, only 21.8% (145) had complications other than seroma (95% CI: 18.7-25.0%), predominantly related to wound infection of the surgical site. The number of complications experience by women varied from 0 to 5 (mean 0.58, SD 0.85) (Table 2). For 6.5% (43) of the sample, complications warranted delayed discharge, readmission to hospital or further procedure and they were thereby classified as having serious complications (95% CI: 4.6-8.4%).

*Univariable analyses*

Participants who underwent mastectomy had a higher mean number of complications (P<0.001), but were no more likely to have serious complications (P = 0.139), compared to those having WLE (Table 1). Similarly those undergoing more extensive axillary node procedures had a higher number of complications (P<0.001) but were not significantly more likely to experience serious complications (P = 0.087). No association was found between number of complications and patient age group (P = 0.512). Similarly the number of complications did not significantly increase with each year of age (IRR 1.02, 95%CI: 1.00-1.04, P = 0.109). Although the proportion experiencing serious complications increased from 4.3% for 70-74 year olds to 10.1% for women aged ≥85 years, this effect failed to reach statistical significance at 5% level; regardless of whether age was measure in groups ($P_{Trend}$ = 0.061) or continuously (two sample t test with equal variances P = 0.060). Participants presenting with larger (P = 0.009), later stage (P = 0.001) tumours and nodal involvement (P < 0.001) had a higher number of complications. However, no tumour characteristics were associated with serious complications.

*Health measures*

Of the 46 separate health measures tested (Box1), 14 were found to be univariately associated with number of complications and 19 with serious complications (Tables 3 & 4) at the 5% level. Bonferroni's adjustment[41] applied (at $\alpha/n = 0.05/46 = 0.001$) is also considered.

Amongst the categorical measures of health (Table 3), smoking status, blood pressure and cognitive impairment (6CIT) had no association with post-surgical complications. At the 5% significance level a BMI indicative of obesity or underweight was associated with a higher count of all complications, but not serious, complications. A dependent ECOG Performance Status and abnormal haemoglobin were associated with both total and serious complications. Co-morbidity (Charlson Index), a high ASA risk score and low platelets were associated with serious complications only. However, none of these measures retained significance once Bonferroni's adjustment was applied at 0.1%.

Of the continuous measures of health (Table 4) lack of functional ability to undertake both basic Activities of Daily Living (e.g. self-care/hygiene) and more advanced 'Instrumental' activities (e.g. shopping/cooking) predicted increased count of all, and odds of serious, complications at the 5% level. However, only Instrumental ADL's prediction of complication count retained significance at the 1% level. Similarly, better physical health status, as measured by the SF-12 PCS, predicted a lower complication count at the 0.1% (Bonferroni adjusted) level but only predicted lower odds of serious complications at the 5% level. Of the 15 EORTC HRQoL domains 10 were associated with complications at the 5% level. However, for most of the domains, the 95% CIs were close to unity (indicating a weak effect) and only 4 domains were significant at the 0.1% level i.e. better physical and role function predicted a lower count of all and serious complications, and increased pain and fatigue predicted having serious and a higher count of complications respectively.

However strongly pre-operative health measures are associated with complications univariately, multivariate analyses are needed to establish the extent to which the health measures continue to predict complications once the effects of potential confounding variables are adjusted for. Therefore, all health measures that significantly predicted complications at the 5% level were considered for inclusion in multivariate analyses adjusting for a range of variables (including extent of surgery, socio-demographics and tumour characteristics) as per the strategy detailed in methods.

In the multivariate analyses a higher count of complications was predicted for women undergoing a mastectomy vs. WLE (IRR 1.64, 95% CI: 1.28-2.12) and more extensive axillary node surgery as opposed to sentinel node biopsy (IRR 1.43, 95% CI: 1.13-1.82) (Table 5). Of the health measures only increased pain predicted outcome, with the total number of complications increasing by 1.006 (95% CI: 1.002-1.011) for each point increase (indicating worsening pain) on the EORTC C30 pain scale.

Neither type of primary surgery nor extent of axillary node procedure predicted odds of serious complications in the multivariate logistic regression analysis (Table 6). Three health measures retained in the model significantly predicted serious complications. Patients with abnormally low platelets had over four times the odds of serious complications compared to patients with normal/high platelets (OR 4.19, 95% CI: 1.03-17.12). The odds of serious complications decreased with higher pulse rate (OR 0.957, 95% CI: 0.926-0.990) and increased by 1.02 (95% CI: 1.006-1.033) times for each point increase (indicating worsening fatigue) on the EORTC C30 fatigue domain. There was no significant difference between the observed and final model predicted values (goodness of fit test $\chi^2$ (Hosmer–Lemeshow) = 7.34: d.f. = 8; P=0.500) and model discrimination (AUC=0.745) is considered 'acceptable'[32]. However, even when the models probability cut point (0.5 by default) was set to 0.063, maximising sensitivity/specificity, these were still low (71.9%) and the false positive/negative rates high (28.1%). In addition, the 95% confidence intervals for all four health measures predicting complications in both final models are close to unity indicating weak effects.

## Discussion

### *Summary*

Although a large proportion (41.0%) of the older women in this study experienced one or more complications these were predominantly seroma or minor infections. A relatively low percentage (6.5%) experienced serious complications which necessitated delayed discharge, readmission or further procedures. More extensive primary and axillary node surgery were associated with a higher number of all complications but not serious complications. Older age did not predict increase in risk of complications. Several health measures were associated with complications univariately. In the multivariate analyses self-reported pain predicted a higher count of all complications whilst fatigue, along with low platelets and pulse rate predicted serious complications.

### *Complication rates*

Previous studies report a wide range of overall rates of breast surgery complications from 2 – 50%[11;42;123]. Although at the higher end of this range our estimates are similar to previous reported studies of older breast cancer patients[17;43;44]; Chat *et al* (2011) for example report overall and major complication rate of 37.1% and 5.7% respectively[43]. Although other studies of older breast cancer patients report somewhat lower overall complication rates (e.g. between 18-26%[45-47]) considerable variation across studies is to be expected depending on co-morbid conditions, time period of data collection/patient follow up, completeness of data sources used as well as the definition and assessment of complications. Rocco *et al* (2013) for example highlight that their estimate of 18.2% among breast cancer patients age ≥65years may be low due to the use of retrospective records from 1997-2012[47]. However, attempts to benchmark breast surgery complication rates have been reported elsewhere[33;43].The aim of the study reported here is to investigate predictors of surgical risk amongst older breast cancer patients.

### *Extent of surgery*

Consistent with previous studies[11;33;43;45], we found that more extensive surgery, both in terms of type of primary surgery (mastectomy vs. WLE) and axillary node dissection, strongly predicted a higher count of all complications. Conversely the extent of surgery did not predict serious complications. This appears contradictory to Chatzidaki *et al*'s (2011) study in which greater extent of surgery predicted major complications. However, the small number of patients experiencing major complications (8/140 participants) limits the generalisability of Chatzidaki *et al*'s findings. In addition, the effect of extent of surgery on all complications may be largely driven by wound complications which have been found to be strongly associated with extent of surgery [11;33]. Wound complications make up a large proportion of complications overall[42] but are underrepresented in our measure of serious complications, which only includes secondary/major wound infections.

*Age*

Older age predicted neither number nor seriousness of complications. Although older age has been found to predict breast surgery complications in earlier[48;49] and smaller scale studies[47], many other studies have found no assoication[11;17;33;44;46]. Notably, in the US-based National Surgical Quality Improvement Program's cohort, older age did not predict wound complications after breast surgery in either the of 3,107 breast cancer patients treated from 2001-2004[33] nor in the follow up study of 26,988 treated from 2005 – 2007[11]. The authors argue that employing multivariate analyses and, controlling for a variety of potentially confounding pre-operative factors, enabled them to demonstrate this in a large and diverse cohort of patients[11]. However, de Glas *et al*[45], in their cohort of 3179 patients diagnosed with breast cancer from 1997-2004, found that women aged ≥85 years had 1.58 the odds of one or more complication following breast surgery compared to 65-69 year olds study (95% CI: 1.14-2.16) after adjusting for comorbidities , surgery type and tumour stage. Hence an increased surgical risk for older breast cancer patients cannot be ruled out; albeit one of a small magnitude limited to the oldest patients.

*Health measures*

Several pre-operative health measures predicted complications in the univariate analyses. As in previous studies co-morbidity[43;45;47], BMI[11;33;43], ASA risk score[14;43] and functional status[14] (as measured by ADL and ECOG Performance Status) demonstrated some association with surgical risk at the 5% level. These findings are far from consistent, with other studies finding no association between surgical risk and co-morbidity[14;46], BMI[45;47], ASA[11] and functional status[33]. Smoking status showed no association with surgical complications in our study. Although the weight of literature indicates that smoking predicts surgical complications from breast surgery[11;45;47;50] this finding is not universal[17;33]. For example, El-Tamer *et al*[33] investigated the influence of a range of patient variables amongst their cohort of 3,107 breast cancer patients and found that smoking had no significant association with post-operative wound complications.

Predictors of surgical risk, identified from studies testing large numbers of pre-operative measures, may only reach statistical significance because of the increased chance of finding an association the greater the number of variables tested. Raising the significance level in line with the total number of variables tested can adjust for this effect (e.g. Bonferroni's adjustment)[41]. Although there are examples in the literature of previous studies investigating risk prediction of large numbers of pre-operative measures for breast surgery[33;43;45], none of the papers cited made either Bonferonni, or similar adjustments. Once Bonferroni's adjustment is applied only 6 of the 22 pre-operative measures which significantly predicted surgical complications at the original 5% level remain significant at the reassigned 1% level. Consistent with a previous study investigating surgical risk of solid tumours[14], increasing dependence in instrumental IADL (e.g. shopping, housework) predicted complications along with the SF-12 measure of physical health status and four domains of the EORTC-C30 (pain, fatigue, physical/role function). These measures were originally selected into the main study on ability to predict treatment[7;25], and/or their high validity/reliability particularly in older populations[22], yet they displayed stronger associations with surgical complications than many of the traditional preoperative health measures. Moreover pain and fatigue predicted complications in the final multivariate models although many health measures failed to do so.

Few previous studies have undertaken similar multivariate analyses specifically predicting risk of breast surgery[11;33;45]. However, similar to our study, Audisio *et al*[14] found that moderate/severe self-reported fatigue increased the risk of complications from surgery for solid tumours amongst patients aged ≥70 years, adjusting for type/ stage of tumour, operative severity and patient age/gender. Generalised neuropathic pre-operative pain has been found to be predictive of postoperative pain after surgery for breast cancer[51] but not previously investigated regarding other complications. Conceivably self-reported pain may be acting as a proxy indicator of poorly managed/symptomatic co-morbidities. Contradictory to our results, El-Tamer *et al*[33] found no association between platelets and wound complications after breast surgery adjusting for a range of tumour characteristics, socio-demographics and other pre-operative health measures. This inconsistency may be due to the difference in outcome measures as primary/minor wound infections were not included in our measure of serious complications.  Lower preoperative pulse rate, as a continuous measure, predicted serious complications, suggesting that the underlying conditions indicated by bradycardia (e.g. Ischaemic Heart Disease) may be increasing surgical risk. However when preoperative pulse rate was instead categorised as bradycardia/normal/tachycardia, this became borderline non-significant (P=0.062), possibly because of the low numbers of patients with abnormal pulse rates.

Although the pre-operative measures retained in the final model accounted for the variation in complications more strongly than the eliminated health measures in the modelling process, it should be noted that their effects in the final model are still weak; with 95% CIs around estimates close to unity. Moreover, although discrimination of the final model predicting serious complications (AUC = 0.745) is classified as statistically 'acceptable'[32], sensitivity and specificity only just exceed 70% and false positives/negatives are far from clinically acceptable; with this model failing to predict complications, and incorrectly predicting complications, in almost 30% of cases. Further research is clearly needed to identify/confirm strong predictors of surgical risk for older patients, which demonstrate clinically acceptable levels of discrimination.

A large number of initially significant health measures were narrowed down to relatively few predictors in the final model. Although somewhat disappointing, we would argue that this is due to the thorough statistical process that should be employed particularly when developing tools for clinical use. As potential users of such risk prediction tools, clinicians should be wary and ensure that the claimed prediction of such assessments are not due to multiple testing, without correction for the increase chance of finding a significant effect (such as Bonferonni), that multivariate analyses (adjusting for potential confounders) were undertaken and sensitivity/ specificity as well as overall discrimination are reported. No located previous literature investigating prediction of complications from breast surgery met all these criteria. As part of the US-based National Surgery Quality Improvement Programme, El-Tamer *et al*[33], comes closest; reporting a similar reduction in variables in the final model and model discrimination just slightly lower than our model (AUC 0.709 vs. 0.745).

*Conclusions*

This paper reports results of a large prospective cohort investigating surgical complications for older breast cancer patients treated the UK, testing prediction of an unprecedented range of pre-operative health measures and adjusting for extent of surgery, tumour characteristics and socio-demographics in multivariate analyses. In the final models self-reported pain predicted a higher count of all complications while fatigue, along with low platelets and pulse rate, predicted serious complications. However, the effects were weak: with 95% confidence intervals close to unity and low sensitivity and specificity.

This analysis was a secondary aim for our study and as such was limited to the sample size, geographical area and pre-operative health measures included in the main study. Other limitations of the main study are discussed elsewhere[7]. Of most relevance to the analysis reported here is the under-representation of women aged ≥85 years; limiting the generalisability of these findings to the oldest age group. However, under-representation of the oldest patients in any study requiring patient consent is likely as capacity for informed consent decreases with older age[52]. Future studies need to either focus on the oldest age group with ethical approval for vulnerable adults/ consent by proxy or examine a few pre-operative health measures that most strongly predict risk within routine/large clinical datasets collected for all patients.

Although universal models for surgical risk prediction based on large clinical data sets have been developed in the US[10] the search for robust predictors of surgical risk for older breast cancer patients in the UK continues. However, focusing on surgery for solid tumours with greater surgical risk[14] may be of greater utility. Clinicians need to ensure that risk prediction of proposed health assessments is not due to multiple testing, that potential confounders are adjusted for and that sensitivity/specificity is clinically sufficient.

Allowing for the potential selection bias due to the need to consent older patients and the reduced proportion of patients aged ≥85 years, the risk of serious complications from breast surgery for older patients in this sample is relatively low and did not increase significantly with age. This supports national guidance which asserts that older age in itself should not be a consideration when planning surgical treatment with older breast cancer patients[4].

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## Tables and figures

**BOX 1: Independent variables**

**Type of surgery i.e. Wide Local Excision vs. Mastectomy**

**Extent of axillary node procedures i.e. Sentinel Node Biopsy vs. Axillary Node Surgery**

**Health measures at pre-operative assessment**

- Blood pressure (low, normal, high)
- Body Mass Index (underweight, normal, overweight, obese)[a]
- Smoking status (current, non-smoker)[a]
- Blood tests (9 both continuous and categorical)[b]
- Pulse (beats per minute)
- Co-morbidity (Charlson Index)[53]
- American Society of Anaesthesiologists (ASA) physical status classification[54]

**Health measures self-reported/assessed at pre-operative interview**

- Functional status:

Eastern Co-operative Oncology Group Performance Status (ECOG-PS)[55]

Elderly Population Health Survey – Activities of Daily Living (ELPHS ADL) Basic/ Instrumental[56]

- Health status (Short Form-12: Physical & Mental Component Summaries)[57]
- Health Related Quality of Life (EORTC C30 = 15 separate scales)[58]
- 6 item Cognitive Impairment Test (6CIT)[59]

**Tumour Characteristics (pre-operative)[28]**

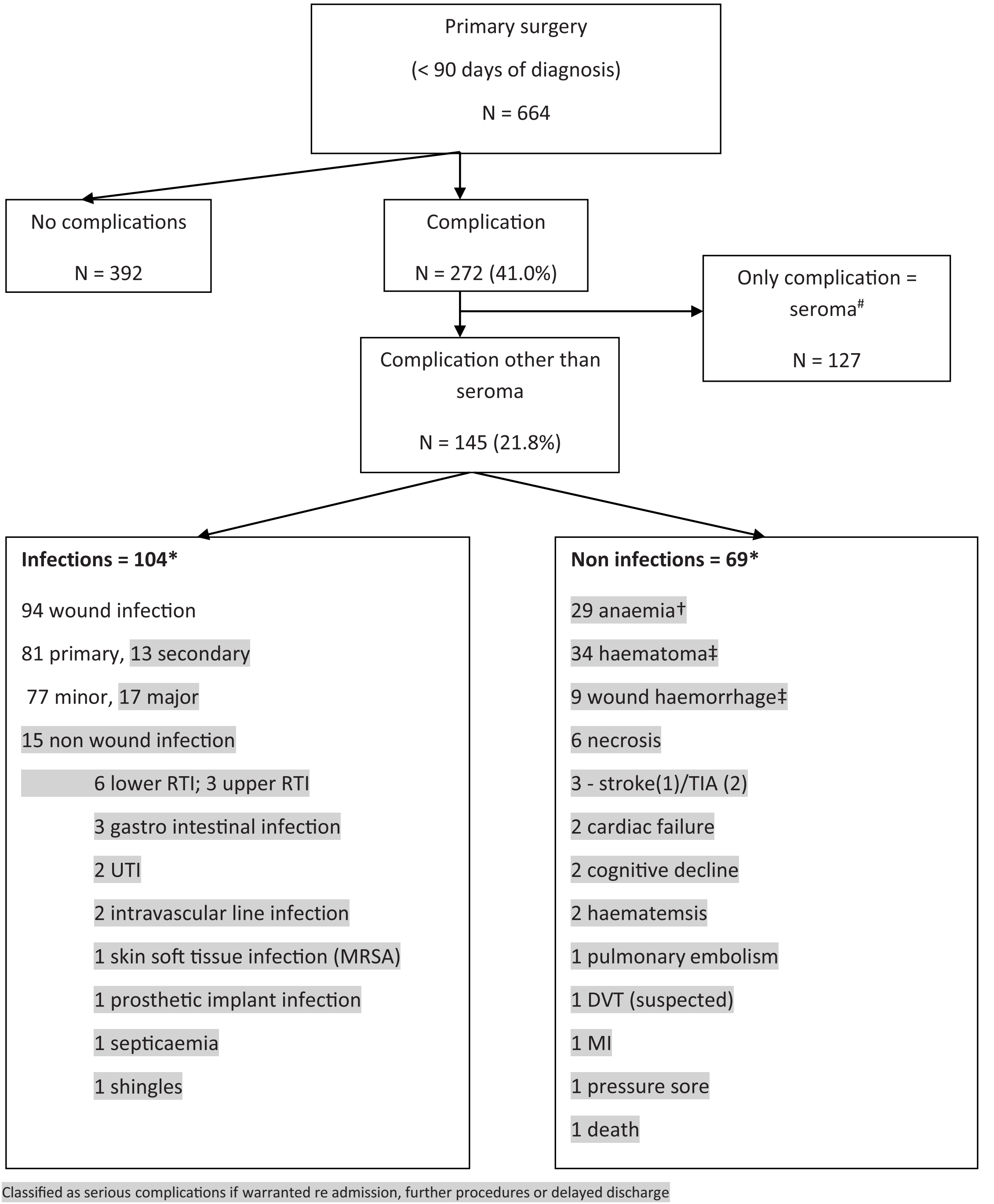
- Tumour size (mm)
- Stage
- Nodal involvement
- Grade
- Steroid Receptor Status (Oestrogen & Progesterone receptor positive or negative)

**Socio-demographics**

- Age
- Socio – Economic Classification[29]
- Type of hospital treated at i.e. university/teaching vs. district

a. Taken from self-report at interview if pre-operative measures not reported in case notes
b. Test Included if recorded at pre-operative assessment for at least 85% of total sample

**FIGURE 21: Flow diagram of complications within 30 days of breast surgery**




Classified as serious complications if warranted re admission, further procedures or delayed discharge

# Only drained seromas recorded.

*Totals not summative. Infections based on the national prevalence survey of hospital acquired infections[19]. Non infections based on a checklist developed from the East Anglian Hip Fracture Audit[16] & Pre-operative Assessment of Cancer in the Elderly Project[14].

† Patients with low haemoglobin (<11.8g/L) pre-operatively were not included unless post-operative blood transfusion. ‡ 6 cases recorded as both hematoma and wound haemorrhage counted as one complication as insufficient information recorded in case notes to distinguish.

### TABLE 51: Surgery, socio demographics and tumour characteristics by 30 day surgical complications

| Variable | Category | n | Percent | All complications - Count | | Serious complications - ≥1 | | |
|---|---|---|---|---|---|---|---|---|
| | | | | Mean (SD) | P* | n | Percent | P* |
| Primary surgery | Mastectomy | 329 | 49.5 | 0.80 (0.95) | | 26 | 7.9 | |
| | WLE | 335 | 50.5 | 0.38 (0.68) | **<0.001[e]** | 17 | 5.1 | 0.139[b] |
| Axillary Node Procedure† | SNB only | 397 | 59.8 | 0.45 (0.74) | | 19 | 4.8 | |
| | ANS | 262 | 39.5 | 0.80 (0.97) | | 24 | 9.2 | |
| | No ANP | 5 | 0.8 | 0.20 (0.45) | **<0.001[e]** | 0 | 0.0 | 0.087[c] |
| Age group (years) | 70-74 | 257 | 38.7 | 0.55 (0.81) | | 11 | 4.3 | |
| | 75-79 | 201 | 30.3 | 0.57 (0.83) | | 15 | 7.5 | |
| | 80-84 | 127 | 19.1 | 0.65 (0.83) | | 9 | 7.1 | |
| | 85+ | 79 | 11.9 | 0.65 (1.04) | 0.512[e] | 8 | 10.1 | 0.061[a] |
| Socio-economic classification | Professional | 358 | 53.9 | 0.60 (0.85) | | 24 | 6.7 | |
| | Intermediate | 169 | 25.5 | 0.56 (0.84) | | 8 | 4.7 | |
| | Manual | 131 | 19.7 | 0.55 (0.79) | 0.792[e] | 9 | 6.9 | 0.664[c] |
| | Missing | 6 | 0.9 | 1.00 (2.00) | 0.922[e] | 2 | 33.3 | 0.093[c] |
| Ethnicity | White | 643 | 96.8 | 0.58 (0.84) | | 41 | 6.4 | |
| | Other | 14 | 2.1 | 0.71 (0.73) | 0.281[e] | 0 | 0.0 | 1.000[c] |
| | Missing | 7 | 1.1 | 1.14 (1.86) | 0.496[e] | 2 | 28.6 | 0.093[c] |
| Hospital type | Teaching/Uni | 287 | 43.2 | 0.55 (0.86) | | 17 | 5.9 | |
| | District | 377 | 56.8 | 0.61 (0.85) | 0.189[e] | 26 | 6.9 | 0.614[b] |
| Tumour stage | I | 293 | 44.1 | 0.48 (0.78) | | 22 | 7.5 | |
| | II & IIIa[d] | 371 | 55.9 | 0.67 (0.90) | **0.001[e]** | 21 | 5.7 | 0.337[b] |
| Nodes involved | Yes | 197 | 29.7 | 0.72 (0.87) | | 13 | 6.6 | |
| | No/NR | 467 | 70.3 | 0.53 (0.84) | **<0.001[e]** | 30 | 6.4 | 0.933[b] |
| Tumour size | ≤20mm | 374 | 56.3 | 0.52 (0.81) | | 27 | 7.2 | |
| | >20≤50mm | 260 | 39.2 | 0.66 (0.89) | | 13 | 5.0 | |
| | >50mm | 15 | 2.3 | 1.07 (1.10) | **0.009[e]** | 2 | 13.3 | 0.203[c] |
| | Missing | 15 | 2.3 | 0.40 (0.51) | **0.021[e]** | 1 | 6.7 | 0.302[c] |
| Grade | 1 | 112 | 16.9 | 0.58 (0.89) | | 8 | 7.1 | |
| | 2 | 347 | 52.3 | 0.57 (0.88) | | 25 | 7.2 | |
| | 3 | 146 | 22.0 | 0.59 (0.73) | 0.541[e] | 7 | 4.8 | 0.414[a] |
| | Missing | 59 | 8.9 | 0.64 (0.92) | 0.656[e] | 3 | 5.1 | 0.781[c] |
| ER or PR Positive | Yes | 555 | 83.6 | 0.59 (0.87) | | 35 | 6.3 | |
| | No | 68 | 10.2 | 0.62 (0.83) | 0.585[e] | 6 | 8.8 | 0.435[c] |
| | Missing | 41 | 6.17 | 0.51 (0.71) | 0.824[e] | 2 | 4.9 | 0.684[c] |
| **Total** | | **664** | **100%** | | | **43** | **6.5%** | |

WLE Wide Local Excision.
SNB Sentinel Node Biopsy only. ANS Axillary Node Surgery.
ER Oestrogen Receptor. PR Progesterone Receptor
† Most extensive ANP Axillary Node Procedure.
* P values for each variable for complete data reported first followed by data including missings if relevant.
Bold p values significant at 5% level.
a. Chi squared test for trend: b. Chi squared Person: c. Fisher's exact test
d. Includes 14 patients with stage IIIa: e. Kruskal–Wallis χ2 adjusted for ties

**TABLE 52: Distribution of 30 day surgical complications**

| Count of complications | Frequency | % |
|---|---|---|
| 0 | 392 | 59.0 |
| 1 | 188 | 28.3 |
| 2 | 62 | 9.3 |
| 3 | 14 | 2.1 |
| 4 | 6 | 0.9 |
| 5 | 2 | 0.3 |
| **Total** | **664** | **100.0** |

Mean number of complications = 0.58, SD = 0.85, Variance = 0.73.
Count of complications does not follow a Poisson distribution as mean ≠ variance.

## TABLE 53: Pre-operative health measures (categorical) by 30 day surgical complications

| Variable | Category | n | Percent | All complications - Count | | Serious complications - ≥1 | | |
|---|---|---|---|---|---|---|---|---|
| | | | | Mean (SD) | P* | *n* | Percent | P* |
| Charlson Co-morbidity | 0 | 371 | 55.9 | 0.53 (0.79) | | 20 | 5.4 | |
| | 1 | 179 | 27.0 | 0.59 (0.86) | | 9 | 5.0 | |
| | 2+ | 114 | 17.2 | 0.75 (1.02) | 0.195[e] | 14 | 12.3 | **0.028[f]** |
| Body Mass Index | <18.5 | 9 | 1.4 | 0.89 (0.93) | | 2 | 22.2 | |
| | 18.5 – 24.9 | 201 | 30.3 | 0.48 (0.78) | | 11 | 5.5 | |
| | 25-29.9 | 238 | 35.8 | 0.55 (0.86) | | 15 | 6.3 | |
| | 30+ | 216 | 32.5 | 0.70 (0.89) | **0.019[e]** | 15 | 6.9 | 0.253[c] |
| Smoker | No | 612 | 92.2 | 0.58 (0.84) | | 39 | 6.4 | |
| | Yes | 52 | 7.8 | 0.65 (0.95) | 0.761[e] | 4 | 7.7 | 0.766[c] |
| Blood pressure (mmHg)[a] | Normal | 186 | 28.0 | 0.56 (0.78) | | 11 | 5.9 | |
| | High >140/90 | 411 | 61.9 | 0.59 (0.84) | | 25 | 6.1 | |
| | Low <90/60 | 41 | 6.2 | 0.63 (1.07) | 0.978[e] | 5 | 12.2 | 0.305 [c] |
| | Missing | 26 | 3.9 | 0.65 (1.13) | 0.994[e] | 2 | 7.7 | 0.395 [c] |
| Pulse (beats/min) | Normal | 538 | 81.0 | 0.58 (0.85) | | 35 | 6.5 | |
| | High ≥100 | 32 | 4.8 | 0.41 (0.56) | | 0 | 0.0 | |
| | Low <60 | 45 | 6.8 | 0.76 (0.93) | 0.226[e] | 6 | 13.3 | 0.062[c] |
| | Missing | 49 | 7.4 | 0.59 (0.91) | 0.395[e] | 2 | 4.1 | 0.120[c] |
| ECOG PS | 0-1 | 476 | 71.7 | 0.52 (0.80) | | 21 | 4.4 | |
| | 2-4 | 170 | 25.6 | 0.78 (0.97) | **0.001[e]** | 19 | 11.2 | **0.002[b]** |
| | Missing | 18 | 2.7 | 0.50 (0.62) | **0.004[e]** | 3 | 16.7 | **0.002[c]** |
| ASA | 1-2 | 411 | 61.9 | 0.57 (0.82) | | 23 | 5.6 | |
| | 3-4 | 155 | 23.3 | 0.70 (0.95) | 0.097[e] | 18 | 11.6 | **0.014[b]** |
| | Missing | 98 | 14.8 | 0.47 (0.80) | 0.054[e] | 2 | 2.0 | **0.007[c]** |
| 6CIT cog impairment | ≤ 7 none | 518 | 78.0 | 0.58 (0.85) | | 35 | 6.8 | |
| | >7 mild/mod | 76 | 11.5 | 0.61 (0.87) | 0.812[e] | 1 | 1.3 | 0.071[c] |
| | Missing | 70 | 10.5 | 0.59 (0.88) | 0.971[e] | 7 | 10.0 | 0.061[c] |
| Blood results[d] | | | | | | | | |
| Haemoglobin | Low | 75 | 11.3 | 0.75 (0.97) | | 9 | 12.0 | |
| | Normal | 482 | 72.6 | 0.52 (0.80) | | 21 | 4.4 | |
| | High | 43 | 6.5 | 0.72 (0.77) | **0.016[e]** | 5 | 11.6 | **0.008 [c]** |
| | Missing | 64 | 9.6 | 0.78 (1.05) | **0.014[e]** | 8 | 12.5 | **0.003 [c]** |
| Platelets | Low | 13 | 2.0 | 0.85 (1.07) | | 3 | 23.1 | |
| | Normal | 555 | 83.6 | 0.56 (0.82) | | 32 | 5.8 | |
| | High | 21 | 3.2 | 0.24 (0.54) | 0.094[e] | 0 | 0.0 | **0.042 [c]** |
| | Missing | 75 | 11.3 | 0.80 (1.07) | 0.055[e] | 8 | 10.7 | **0.032 [c]** |
| **Total** | | **664** | **100%** | **0.59 (0.88)** | | **43** | **6.5%** | |

ECOG-PS Eastern Co-operative Oncology Group – Performance Status 0-5 categories indicating decreasing functional status. ASA American Society of Anaesthesiologists physical status classification system. 6CIT 6 Item Cognitive Impairment Test (scale 0-28: increase indicated worse cognitive impairment 0-7 indicates normal)

a. blood pressure classed as high or low based on limits for hypertension[60] and hypotension[61]

b. Chi squared Person: c. Fisher's exact test

d. 9 blood results investigated. Only reported if significantly associated with complications P<0.05. Neutrophils, Lymphocytes, Sodium, Potassium, Urea, Creatinine and White blood cells therefore not reported. Classification for blood results were based on the National Pathology Harmonisation Standardisation project[26;27]

e. Kruskal–Wallis $\chi 2$ adjusted for ties:

f. Chi squared test for trend

*P values for each variable for complete data reported first followed by data including missings if relevant. Bold p values significant at 5% level. No variables retained significance once Bonferroni's correction applied at α/number of tests = 0.05/46 = 0.001.

**TABLE 54: Pre-operative health measures (continuous) by 30 day surgical complications***

| Variable | n | All complications - Count | | | Serious complications - ≥1 | | |
|---|---|---|---|---|---|---|---|
| | | IRR[a] | 95% CI | P | OR[b] | 95% CI | P |
| **ELPHS ADL Functional Status** 1-4 increase = worse | | | | | | | |
| Basic ADLs | 661 | 1.37 | 1.12 - 1.68 | 0.002 | 2.08 | 1.25 - 3.47 | 0.005 |
| Instrumental ADLs | 648 | 1.26 | 1.11 - 1.43 | <0.001 | 1.65 | 1.15 - 2.36 | 0.006 |
| **SF12 PCS,** 1-100 inc = better | 648 | 0.98 | 0.98-0.99 | <0.001 | 0.97 | 0.94 - 0.99 | 0.006 |
| **EORTC C30 Function Scales, 1-100, increase = better** | | | | | | | |
| Global QoL | 638 | 0.99 | 0.99 - 1.00 | 0.002 | 0.98 | 0.97 - 0.99 | 0.001 |
| Physical | 656 | 0.99 | 0.99 - 1.00 | <0.001 | 0.98 | 0.97 - 0.99 | <0.001 |
| Role | 652 | 0.99 | 0.99 - 1.00 | <0.001 | 0.98 | 0.97 - 0.99 | <0.001 |
| Cognitive | 652 | 0.99 | 0.99 - 1.00 | 0.028 | - | - | - |
| Social | 643 | 0.99 | 0.99 - 1.00 | 0.001 | - | - | - |
| **EORTC C30 Symptom Scales, 1-100, increase = worse** | | | | | | | |
| Fatigue | 652 | 1.01 | 1.00 - 1.01 | 0.001 | 1.02 | 1.01 - 1.04 | <0.001 |
| Pain | 655 | 1.01 | 1.00 - 1.01 | <0.001 | 1.01 | 1.00 - 1.02 | 0.025 |
| Dyspnoea | 655 | 1.01 | 1.00 - 1.01 | 0.003 | 1.01 | 1.00 - 1.02 | 0.027 |
| Constipation | 652 | - | - | - | 1.01 | 1.00 - 1.02 | 0.026 |
| Appetite Loss | 654 | - | - | - | 1.01 | 1.00 - 1.02 | 0.044 |
| **Pulse** (beats/minute) | 615 | - | - | - | 0.96 | 0.93 - 0.98 | 0.002 |
| **Blood results** | | | | | | | |
| Sodium (mmol/l) | 613 | - | - | - | 0.89 | 0.82 - 0.98 | 0.012 |
| Potassium(mmol/l) | 608 | - | - | - | 2.53 | 1.20 - 5.34 | 0.015 |

a. Incident Rate Ratios generated by univariable negative binomial regression.
b. Odds Ratios generated by univariable logistic regression.
ELPHS ADL, Elderly Population Health Status Survey's Activity of Daily Living (scale 1–4: increase indicates worse functional status). Basic ADLs include basic self-care and mobility. Instrumental ADLs include more advanced activities such as housework and shopping; SF-12, Short Form 12 Physical Component Summary (scale 1–100: increase indicates better health); EORTC QLQ-C30, European Organization for Research on Treatment of Cancer Quality of Life Questionnaire (version 3) Global Quality of Life scale 1–100: increase indicates better health.
* Health measures only reported if significantly associated with complications P<0.05. Following measures therefore not reported above; EORTC QLQ-C30 Emotional Functioning, Insomnia, Financial Problems, Nausea/Vomiting and Diarrhoea; SF-12, Short Form 12 Mental Component Summary; Blood results: Urea, Creatinine, Haemoglobin, Platelets, White Blood Cells, Neutrophils, Lymphocytes
Underlined P values indicate that significance retained once Bonferroni's correction applied at α/number of tests = 0.05/46 = 0.001.

**TABLE 55: Multivariable negative binomial regression model predicting count of all 30 day surgical complications (n = 622)**

| Variable* | | Adjusted IRR‡ | SE | P** | 95% CI Lower | 95% CI Upper |
|---|---|---|---|---|---|---|
| Primary Surgery | WLE | (ref) | - | - | - | - |
| | Mastectomy | **1.642** | **0.212** | **<0.001** | **1.274** | **2.115** |
| Axillary Node Procedure† | SNB only | (ref) | | | | |
| | ANS | **1.433** | **0.173** | **0.003** | **1.131** | **1.816** |
| | No ANP | 0.460 | 0.477 | 0.454 | 0.060 | 3.504 |
| EORTC Global QoL, 1-100, inc = better | | 0.996 | 0.003 | 0.207 | 0.991 | 1.002 |
| EORTC Pain, 1-100, inc = worse | | **1.006** | **0.002** | **0.004** | **1.002** | **1.011** |
| Tumour size (mm) | | 1.004 | 0.004 | 0.340 | 0.996 | 1.013 |
| Constant | | 0.367 | 0.093 | <0.001 | 0.223 | 0.604 |
| Alpha | | 0.188 | 0.112 | | 0.059 | 0.602 |

IRR Incidence Rate Ratio. SE Standard Error. CI Confidence Interval. WLE Wide Local Excision
† Most extensive ANP Axillary Node Procedure. SNB Sentinel Node Biopsy only. ANS Axillary Node Surgery.
‡Adjusted for all other variables in the table
* Health measures BMI, ECOG performance status, Haemoglobin, ELPHS ADL functional status, SF-12 Physical Component Summary, EORTC C30 scales (Physical, Role, Cognitive & Social Functions, Fatigue & Dyspnoea) not included as no significant effect in initial multivariable model. Tumour stage & nodal status were removed as they did not significantly improve fit of model. **P-values <0.05 are shown in bold.

**TABLE 56: Multivariable logistic regression model predicting ≥ 1 serious complication at 30 days post-surgery (n = 537)**

| **Variable*** | | **Adjusted OR‡** | **SE** | **P**** | **95% CI Lower** | **95% CI Upper** |
|---|---|---|---|---|---|---|
| Primary Surgery | WLE | (ref) | | | | |
| | Mastectomy | 1.041 | 0.425 | 0.922 | 0.467 | 2.317 |
| Axillary Node Procedure† | SNB only | (ref) | | | | |
| | ANS | 1.748 | 0.697 | 0.162 | 0.800 | 3.820 |
| Platelets | Normal/high# | (ref) | | | | |
| | Low | **4.189** | **3.009** | **0.046** | **1.025** | **17.123** |
| Pulse (beats/minute) | | **0.957** | **0.016** | **0.010** | **0.926** | **0.990** |
| EORTC Fatigue (1-100, inc= worse) | | **1.019** | **0.007** | **0.004** | **1.006** | **1.033** |
| Constant | | 0.635 | 0.810 | 0.722 | 0.052 | 7.753 |

OR Odds Ratio. SE Standard Error. CI Confidence Interval.
† Most extensive ANP Axillary Node Procedure. SNB Sentinel Node Biopsy only. ANS Axillary Node Surgery. None of the 5 patients having no ANP retained in the final model
‡Adjusted for all other variables in the table
# Retained 19 cases with high platelets amalgamated with 555 cases with normal platelets as high category omitted due to lack of events
* Charlson Co-morbidity, ECOG performance status, Haemoglobin, ELPHS ADL functional status, ASA, Potassium, SF-12 Physical Component Summary and EORTC C30 scales (Global QoL, Physical Function, Role Function, Pain, Dyspnoea, Constipation, Appetite Loss) not included as no significant effect in initial multivariable model. Sodium removed from model as it produced VIFs >100.
**P-values <0.05 are shown in bold.
Goodness of fit test $\chi^2$ Hosmer-Lemeshow = 7.34: d.f. = 8; P = 0.500
Area under Receiver Operator Characteristics curve = 0.745
Sensitivity & Specificity 71.9%, False positive & negative rate 28.1% (probability cutpoint set to 0.062742)

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