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COULD GENERAL SURGEONS WITH SPECIAL INTEREST IN BREAST SURGERY DELIVER A QUALITY SERVICE DESPITE A PARADIGM SHIFT TOWARDS SPECIALISATION? AN IN-DEPTH ANALYSIS OF QUALITY ASSESSMENT-BASED PRACTICE AT A GENERAL SURGEON-LED BREAST UNIT IN THE UNITED KINGDOM

Breast Surgery

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ABSTRACT

Background: Despite specialisation, a small subset of general surgeons continues to provide breast services in the United Kingdom. We aimed to assess breast cancer i) local recurrence rate against the national benchmarks of <5% (for invasive cancer) and <10% (for noninvasive cancer) at 5-year, and ii) net survival rates against national record of 95.8% and 85.3%, at 1-year and 5-year, respectively.
Methods: All breast cancers (between 01/05/2012 and 30/04/2013) at a district general hospital in the north-west of England were audited. Two general surgeons provided the breast service. One surgeon performed mostly excisional surgery and acted as a 'generalist'. The second surgeon also performed level 2 oncoplastic procedures and acted as an internal control as a 'specialist'.
Results: Out of 270 cancers diagnosed, 203 patients underwent surgery. Six patients (out of 180 invasive cancers) developed local recurrences (3.33%). Two patients (out of 23 patients with Ductal Carcinoma-In-Situ) developed local recurrences (8.69%). There was no significant inter-surgeon variation in practice except a difference in the size of the excised lesions. 1-year and 5-year net survival rates amongst all female breast cancer patients were 97% and 87.3%, respectively. Overall survival at 5-year was 79.1%.
Conclusions: The results demonstrate that in an unselected cohort of breast cancer patients, general surgeons with interest in breast surgery can achieve acceptable standards in terms of local recurrence at 5-year, and net survivals at 1-year and 5-year. No conceivable difference in practice between two surgeons with 'generalist' and 'specialist' skill-mix was noted. Low overall survival might reflect wider health issues. This has implications in planning a local breast service and utilising constrained human resources in the era of specialisation.

KEYWORDS

Breast neoplasm, Mastectomy, Local Excision, Specialism, Survival, Mortality

BACKGROUND:

There has been a paradigm shift of generalism towards specialization in breast surgery, which has been actively promoted to ensure that patients see surgeons with a special interest and training in breast surgery (1). However, such a transition has its logistical constraints and some units are still led by general surgeons with interest in breast surgery, rather than stand-alone breast surgeons. Many breast surgeons with on-call responsibility in the United Kingdom (UK) opined that their work in breast surgery was affected by on-call commitments (2). This reflects constrained human resource allocation in the era of specialisation. Planning and utilising a specialised workforce can be complicated, and the economics cannot be ignored. It is no accident that countries with a larger proportion of specialists, like North America or Sweden (where there are ten times as many specialists as generalists), spend considerably more of their gross domestic product (GDP) on health than countries like Netherlands or UK (where there are an equal number of specialists and generalists) (3). It is therefore worth considering how generalization and specialization can play important roles in harmony.

Breast cancer is the commonest female cancer worldwide, with increasing incidence of breast cancer in the UK (4). The last four decades have been characterised by a drive towards specialisation to consolidate specialist skills based on the premise that "practice makes perfect', 'surgical oncologists' are more likely to do breast-conservation surgery than 'general surgeons' and 'higher surgeon volume' correlates with 'better survival' (5-7). This should not come as a surprise as similar volume-outcome relationship has been observed in other specialty, such as colorectal surgery, as well (8). The risk of developing ipsilateral breast local recurrence is related to patient and tumour factors (9). As per meta-analysis by Houssami *et. al.* (2014), achieving a tumour negative margin (a surgeon dependent variable) significantly reduces the risk for ipsilateral breast tumour recurrence (10). It therefore stands to reason why ipsilateral tumour recurrence, which currently approximates to 0.6% per year following breast conserving surgery for invasive cancer, is considered a surrogate marker for quality of breast cancer surgery (11,12).

Irrespective of one's view about generalism or specialization, the quality of service should remain high, reflecting a safe practice that meets the quality assurance. National Institute of Health and Care Excellence (NICE) considers local recurrence and survival as two important quality standards for breast cancer (13). The breast service under consideration is part of a 760-bedded district general hospital with teaching and research affiliations to neighboring universities, catering approximately 440,000 population in the North West of England (14,15). The breast unit deals with approximately 300 new cancers every year. As far as local recurrence is concerned, less than 5% for invasive breast cancer and 10% for non-invasive breast cancer at 5-year are considered benchmarks set by the national bodies (16,17). Net survival rates of female breast cancer patients in England at 1-year and 5-year have been cited by the Office for national statistics as 95.8% and 85.3%, respectively (18).

AIMS:

The primary aim was to ascertain breast cancer local recurrence at 5-year, and disease specific survival (net survival) at 1-year and 5-year, and assess any association with relevant tumour biology and different aspects of individual surgeon's practices.

The secondary aim was to assess breast cancer overall survival at 5-year.

METHODS:

***Setting*:** District General Hospital in the north-west of the UK
***Study period*:** From 01 May 2012- 30 April 2013

Inclusion criteria: All breast cancer patients were included in the study.

***Exclusion criteria*:** (i) Local recurrence study- missing data, non-operated cases and those with DCIS were excluded from detailed tumour characteristics and intervention analysis; (ii) Survival study- Male patients were excluded.

***Type of study*:** Audit involving retrospective analysis of prospectively accrued data.

Study registration: The study was registered with the Audit department. This study was not considered a research by the NHS and formal Research Ethics Committee review was not required, in compliance with national guidelines. Consent was also not required in view of the facts that this was an audit project without any patient participation entailing additional clinical intervention; or sharing of identifiable individual information.

Case-mix and team involvement: All breast cancer cases were discussed routinely in a multidisciplinary meeting preoperatively and postoperatively, and managed as per the national guidelines. Surgical resections were performed by two general surgeons (surgeons A and B). Both were general surgeons with interest in breast surgey. One of the surgeons (surgeon A) performed mostly excisional surgery (i.e., wide local excision, mastectomy and axillary surgery, without therapeutic mammoplasty/ reduction and reconstruction). The other surgeon (surgeon B) performed level 2 oncoplastic surgery, reduction and some implant-based recontsructions as well. This skill-mix acted in a complementary way and patients were randomly allocated to either surgeon, depending on the case-load, clinic and theatre capacity. Random allocation of cases and mixed skill-set allowed an internal comparison between surgeon A ('generalist' skill) and Surgeon B ('specialist' skill). All patients were followed-up regularly up to 5 years.

***Definition*:** i) Local recurrence (Locally recurrent cancer)- Cancer that has recurred at or near the same place as the original (primary) tumor, within 1-year and 5-year following treatment in the ipsilateral breast or thoracic wall has been recorded as local recurrence; ii) Disease-specific survival (Net survival) rate- The percentage of people in the study or treatment group who did not die from a specific disease (breast cancer) in the defined period of time (1-year or 5-year), henceforth referred as Net survival rate; iii) Overall survival rate- The percentage of people in the study group who were still alive for a certain period of time (5-year) after they were diagnosed with the disease (breast cancer) (19).

***Coding*:** Histological diagnosis (C50.0–C50.9) was required for a diagnosis of local recurrence to be made as stated in the International Classification of Diseases version 10 (ICD10) (20).

***Data source*:** Departmental prospective record of tumour occurrences and events (including local recurrence and death), case-notes and electronic archives.

***Data collected*:** Age, tumour characteristics (histology, size, grade, Oestrogen/ Progesterone (ER/PR), Human epidermal growth factor receptor 2 (HER2) status, Tumour and Nodal stage), treatment modalities (surgery, chemotherapy and radiotherapy), local recurrence, survival, and follow-up.

***Statistical analysis*:** Chi-square, Fisher's Exact test, Student's t-test, and Kaplan-Meier tests were performed using SPSS V26 (IBM® corporation, New York, America). A p-value of <0.05 was considered as statistically significant.

RESULTS:

A total of 270 patients, including two male patients, were diagnosed with breast cancer during the study period. We failed to retrieve full information on five patients, who were excluded from further analysis. Out of the remaining 265 patients, 26 had ductal carcinoma in situ (DCIS) and 239 had invasive cancers. Sixty-two patients did not have any breast operation for various reasons. Out of remaining 203 patients, 180 had invasive cancers. Figure 1 illustrates the flow diagram mapping out the number of patients analysed in detail in the study.

Out of two male patients, one was treated with primary endocrine therapy and the other patient underwent surgery for invasive cancer.

Various tumour characteristics such as histology, grade, Oestrogen/ Progesterone (ER/PR) and Human epidermal growth factor receptor 2 (HER2) status, Tumour (T) and Nodal (N) stage were assessed. Different interventions, namely type of surgery, such as breast conserving surgery (BCS) or mastectomy, as well as radiotherapy and chemotherapy were also evaluated. The results have been summarized in Table 1.

Table 2 shows distribution of tumour characteristics and interventions according to the practice of surgeons. There were no statistical differences noted in the surgical practices except the size of the lesions excised.

Six patients (out of a total of 180 invasive cancers) developed local recurrences (3.33%). Two patients (out of a total of 23 patients with DCIS) developed local recurrences (8.69%). No significant associations were noted between individual surgeon's practice and local recurrence for invasive cancers (p=0.21; Hazard Ratio 0.27), as shown in Table 3 and Kaplan-Meir curve illustration [Figure 2]. Local recurrence was noted to be higher in the group of patients whose tumours were ER/PR negative (n=3; 20% of 15), compared to those with ER/PR positive tumours (n=3; 1.8% of 165) [p=0.008]. Possible correlations amongst local recurrence and various tumour characteristics were assessed and no significant association was found (p>0.05).

Net survival was evaluated at two settings [Table 4].

[A] Out of 270 patients who were diagnosed with breast cancers, two were males, who were excluded from further analysis. Fifty-six patients deceased due to various causes during the 5-year study period (all-cause mortality 20.9%; overall survival 79.1%). By considering breast cancer related deaths only, the incidence of net survival amongst 268 female patients was noted to be 260 and 234 at the end of 1-year and 5-year, respectively. This corresponded to 1-year and 5-year net survival rates 97% and 87.3%, respectively. The median age of deceased patients at the end of 5-years was 76 years (range, 50-100**).**

[B] Out of 180 patients who underwent surgery for invasive cancers, one was a male patient, who was excluded from further analysis. The incidence of net survival amongst remaining 179 female patients was 177 and 164 at the end of 1-year and 5-year, respectively**.** This corresponded to 1-year and 5-year net survival rates of 98.9% and 91.6%, respectively. The median age of deceased patients at the end of 5 years was 73 years (range, 57-88).

There was a significant difference in the occurrence of 5-year net mortality between practices of two consultants when 'all' female breast cancer patients were considered (p=0.02). However, the analysis of 5-year net mortality amongst those who 'underwent surgery for invasive cancer', did not show any significant difference (p=0.49) [Table 4]. These findings were confirmed when survival over time was further estimated by Kaplan-Meier analysis, as illustrated in Figures 3 and 4.

DISCUSSION:

Generalism versus specialisation debate is not new. Both have proponents. There is strong evidence that health systems with a generalist orientation achieve better outcomes at lower costs (21). Specialists provide more complex care that may warrant special settings. However, human resources are limited. Even if the specilist skill is available, redirecting such skill creates a void somewhere else. For example, a surgeon dedicated to breast service may not be available to take part in general surgery on-call rota (22). Loss of generalist skill is also another factor, that can develop over time, particularly if someone is focused on the specialist work only. With subspecialisation, fewer and fewer new breast surgeons now take part in emergency general surgery (23).

Local recurrence at five years has been described as a surrogate marker for quality of surgery by the association of breast surgeons (12). Ipsilateral breast tumour recurrence is an independent risk factor for distant metastases and survival (24,25). Hence the current study was undertaken to assess the performance of the unit in terms of local recurrence following breast cancer surgery and net survival. However, as outlined in Figure 1, we encountered few missing observations, not uncommon in a retrospective analysis (26). No particularly unusual finding stood out in the occurrence of different invasive tumour characteristics and interventions [Table 1].

Patient and tumour characteristics have been identified as predictive risk factors for breast cancer recurrence (24). That's why any correlation with relevant tumour biology was assessed in our study. A statitically significant difference in the size of the excised lesions was noted. This could be explained by the fact that surgeon B, who also performed level 2 oncoplastic procedures, most likely undertook therapeutic mammoplasties for large lesions and hence operated more on larger tumours requiring breast conservation. Otherwise, there was no significant difference in the workload of two surgeons. Perhaps not unexpectedly, local recurrence was found to be inversely associated with ER/PR status, reflecting inherent good prognosis of ER/PR positive tumour [Table 2].

There is a large body of evidence available supporting better outcomes for complex surgery with respect to hospital and surgeon volume and specialization (5,8,27,28). Surgeon's specialty had been reported to be significantly associated with long term outcomes, although the mechanisms underpinning such association remained unclear (29). Therefore, the jury is still out on the relationship between surgeon volume and specialisation and ipsilateral breast cancer recurrence. This would explain our rationale to compare practice of one surgeon (considered close to that of a 'generalist') with the other (a 'specialist'), although both were general surgeons with on-call commitments and performed general surgery as well. Local recurrence of 8.69% for non-invasive breast cancer satisfied the national benchmark of <10% at 5-year. 5-year local recurrence rate of 3.33% for invasive breast cancer was also well within <5% recommended level. These are very reassuring. It has been cited that specialisation reduces the risk of local recurrence (7,28). Hence we hypothesised that practice of surgeon A ('generalist') was a high risk for local recurrence. However, Hazard Ratio of 0.27 (95% CI 0.05-1.4) ruled out any such association [Table 3]. Also, there was no difference in terms of occurrence of local recurrence for invasive cancers in the hands of individual surgeons, when ploted against time of occurrence [Figure 2].

Occurrence of male breast cancer was 0.75%. This is in accordance with expected 0.5-1% male breast cancer incidence (30). Both the male patients were excluded from the survival analysis, as described below.
Office for National Statistics holds records of net survival rates for the female breast cancer in England, which was accepted as a gold standard (17). In this study, male patients were excluded from survival analysis as the survival records provided by Office for National Statistics applied to female patients only. Survival was difficult to assess. Following death of a patient in the hospital, the system automatically generates a record confirming that the patient has deceased. However when a patient dies in the community, or at another hospital, such records are not always easy to come by. Hence every effort was made to obtain the relevant information. Furthermore, one must also be mindful that non-breast cancer causes of death (mainly heart and cerebrovascular diseases) represent a significant number of deaths among patients with breast cancer, and should be taken into account regarding future health risks of breast cancer survivors (31). Putting in context, the overall survival (in contrast to breast cancer-specific net survival) of 79.1%, as found in this study, is likely to reflect wider socio-economic and health background. It is noteworthy that as per the Office for the National Statistics, female life expectancy of the catchment (study) population catered by the our hospital is 79.5 years, compared to 83.1 years in England (a gap of 3.6 years) (32). The various factors that create this long-term, structural gap in life expectancy between the said population in the north-west and remainder of England remain to be explored and are beyond the remits of this study (32,33).

Net survival rates amongst 'all female patients' who were diagnosed with breast cancers (n=268) at 1-year and 5-year were 97% and 87.3%, respectively, and evidently better than corresponding national levels of 95.8% and 86.6%. This is reassuring. A significant difference of 5-year net survival rates of all females who were diagnosed with breast cancer between two surgeons was noted, confirmed on comparison against various time points of survival (p=0.02) [Table 4]. However corresponding Hazard ratio of 2.1 was associated with a wide ranging confidence interval (1.07-4.1), casting doubt on the certainty of the significance. The figures did not appear to be clinically significant, as it most likely reflected allocation of patients rather than surgeons' surgical abilities, as exemplified by the sub-group analysis further. A sub-group analysis of 5-year net survival rate amongst females who underwent surgery for invasive cancer (the group that is likely to show a poorer survival rate, if surgical decisions or procedures were not carried out appropriately) was 91.6% (up by 4.3%, compared to 87.3% survival of 'all patients who had breast cancer') [Table 4]. Interestingly, no significant difference persisted in the occurrence of survival between practices of two consultants, which was also assessesd against time scale of survival (p=0.49) [Figure 4]. Improved survival figure in the sub-group of female patients who underwent surgery for invasive cancer, compared to 'all patients who had breast cancer', suggests that the better survival was because of, not despite surgical intervention.

Oncoplastic surgery, currently an integral part of breast cancer surgery in the UK, has been associated with lower margin involvement, lesser re-excision in breast conservation and higher completion mastectomy rate, as well as higher operating time and complication profile (34,35). The current study did not show any clinically significant differences in outcomes between two surgeons, one of whom provided oncoplastic surgery [Tables 2, 3 and 4].

Patients treated by low-workload surgeons have been correlated with poorer survival (7). A significant challenge in the volume-outcome relationship is the heterogeneity in the definitions of 'volume cut off', required to achieve an acceptable outcome (34). Approximately 100 annual incident breast cancer patients are considered to meet the threshold for high– volume breast cancer hospitals in the United States, Canada, and Japan (36). Hopkins University recommends to choose a breast surgeon who does 50 or more breast cancer operations a year (37). In the current study, each surgeon dealt with an average of 135 cancer cases per annum and surgeon-volume was 90 per year, in accordance with the numbers expected for a breast surgeon working in a high-volume unit.

Is it possible to replicate our experience in a different set-up? For example, general surgeons in United States of America (USA) still delivers surgery for breast cancer, which constitute 14-25% of their practice. There have been calls for a more breast focused approach and that all breast surgery be performed by oncoplastic surgeons, which is an extreme end of the argument of course (6,38). We propose, based on the findings of our study, a pathway that can be a safe compromise between two extreme approaches. There are subsets of patients who have small tumours in favourable locations in the breast that do not warrant oncoplastic procedure per *se*, are not necessarily suitable for long oncoplastic surgery due to co-morbidities, or would prefer 'simple excisional surgery' (patient's choice), could satisfactorily be operated on by the general surgeons (35). It must be emphasized that if general surgeons are to offer breast surgery, the practice must be exclusively within a multi-disciplinary team setting to ensure adherence to protocols and guidelines. A plausible and pragmatic approach to address the increasing demand on the oncoplastic service would be to identify suitable patients, who can be for satisfactorily managed by the general surgeons.

We acknowledge the limitations of the study. Most importantly, a randomised trial would have been the best way to address the question rasied in our study. Also, the findings can potentially be prone to statistical errors due to relatively small number of patients and missing data. However, the allocation of patients to two surgeons in this study, although not controlled, did take place in a random fashion, guided by the case-load and capacity requirement. In fact, our mixed-skill set-up that works in a complementary way and unison, reflects a balanced working pattern common to most of the well functioning units and therefore, is indicative of a real-life scenario and adds to the strength of study (39). Even if we focus on the unit performance as a whole only, low local recurrence and high survival rates would still support our conclusion that as a general-surgeon led breast unit we met two important national quality standards.

Despite the limitation of the time frame and nature of the analysis, the strengths of the study lie in the fact that it adds constructively to the debate of 'generalisit *versus* specialist' in breast surgery, suggests a pathway that allows selective cases that are suitable for management by the general surgeons and is relevant in the setting of constrained human resources.

CONCLUSIONS:
The results demonstrate that in an unselected cohort of breast cancer

patients, general surgeons with interest in breast surgery can achieve acceptable standards in terms of local recurrence at 5-years and net survivals at 1-year and 5-year. No conceivable difference in practice between two surgeons with 'generalist' and 'specialist' skill-mix was noted. Low 5-year overall survival might reflect wider health issues. It is possible for general surgeons with skill-mix and special interest in breast surgery, to provide a quality breast service at a local level. This must be interpreted in the light of changing patient expectations and quality assurances needed to adhere to national guidelines, and provid ing breast service within the constraints of available human resources.

Table 1. A summary of different invasive tumour characteristics and interventions (n=180).

Tumour characteristics			
Histology	IDC	144	(80.0%)
	ILC	30	(16.7%)
	Other	6	(3.3%)
Grade of tumour	I	19	(10.6%)
	II	109	(60.6%)
	III	52	(28.9%)
ER/ PR status	Negative	15	(8.3%)
	Positive	165	(91.7%)
HER2 status	Positive	16	(8.9%)
	Negative	164	(91.1%)
T stage	T1	91	(50.6%)
	T2	70	(38.9%)
	T3	15	(8.3%)
	T4	4	(2.2%)
N Stage	N0	128	(71.1%)
	N1	38	(21.1%)
	N2	10	(5.6%)
	N3	4	(2.2%)
Interventions			
Surgery	Mastectomy	72	(40.0%)
	BCS	108	(60.0%)
Chemotherapy	Yes	69	(38.3%)
	No	111	(61.7%)
Radiotherapy	Yes	131	(72.8%)
	No	49	(27.2%)

(IDC= Invasive Ductal Carcinoma; ILC= Invasive Lobular Carcinoma; ER/PR= Oestrogen/ Progesterone; HER2= Human Epidermal Growth Factor Receptor 2; T Stage= Tumour stage; N Stage= Nodal stage)

Table 2. Distribution of age, invasive tumours characteristics and interventions as per individual surgeon's practice (n=180).

		Surgeon A	**Surgeon B**	**p-value**
Median Age (year)		64 (range, 30-90)	60 (range, 36-89)	0.59
Histology				
	Ductal	64	80	0.61
	Lobular	10	20	
	other	00	06	
Grade				
	I	07	12	0.61
	II	48	61	
	III	19	33	
Mean tumour size (mm ±SD)		21.9 ±13.3	27.07 ±20.6	**0.01**
ER /PR status				
	Positive	69	96	0.52
	Negative	05	10	
HER2 Status				
	Positive	06	10	0.75
	Negative	68	96	
T Stage				
	T1	42	49	0.24
	T2	28	42	
	T3	03	12	
	T4	01	03	
N Stage				
	N0	54	74	0.44
	N1	16	22	
	N2	04	06	
	N3	00	04	
Type of surgery				
	BCS	48	60	0.26
	Mastecto my	26	46	
Chemotherapy				
	Yes	25	44	0.29
	No	49	62	
Radiotherapy				
	Yes	52	79	0.32
	No	22	27	
Median Follow-up (month)		65 (range, 6-88)	66 (range, 18-90)	0.20

(SD= standard deviation; ER/PR= Oestrogen/ Progesterone; HER2= Human Epidermal Growth Factor Receptor 2; T Stage= Tumour stage; N Stage= Nodal stage; BCS= Breast conserving surgery)

Table 3. Occurrence of local recurrence in patients who underwent excision of primary invasive breast cancer (n=180), as per the consultant's practice.

	Local recurrence		p-value	HR (95% CI)
	Yes	No		
Surgeon A	1	073	0.21	0.27 (0.05-1.4)
Surgeon B	5	101		

(HR= Hazard Ratio; CI= Confidence Interval)

Table 4. Occurrence of survival at 5-year as per consultant's practice.

	Surgeon A	**Surgeon B**	**p-value**	**HR (95% CI)**
All female patients "diagnosed with breast cancer" (n=268) [Net survival 87.3%]				
Died of breast cancer	21	13	**0.02**	2.1 (1.07-4.1)
Alive/ died of non-breast cancer causes	101	133		
Median age of the deceased (year)	73 (Range, 50-95)	78 (Range, 54-100)	0.45	
Female patients "who had surgery for invasive cancer" (n=179) [Net survival 91.6%]				
Died of breast cancer	10	05	0.49	1.45 (0.52-4.04)
Alive/ died of non-breast cancer causes	95	69		
Median age of the deceased (year)	78 (Range, 57-88)	69 (Range, 63-78)	0.35	

(HR= Hazard Ratio; CI= Confidence interval)

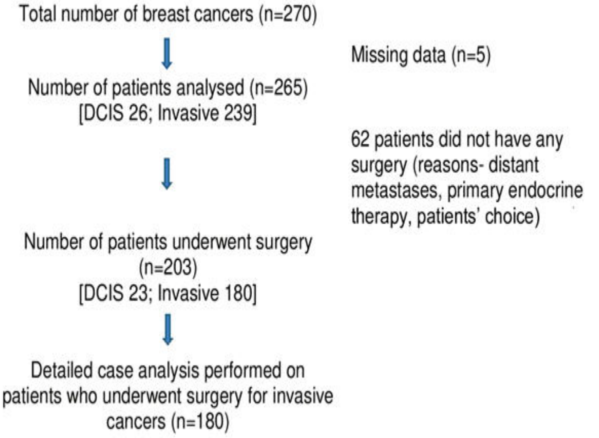

Figure 1. Flow diagram of record and analysis of patients.

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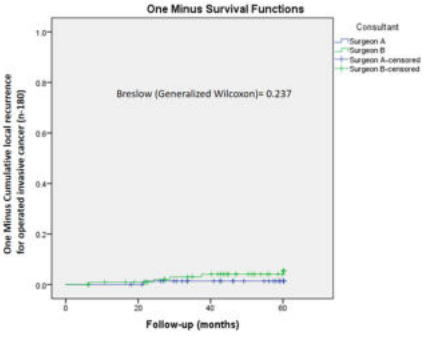

Figure 2. Kaplan-Meier curve showing local recurrence for operated invasive breast cancers.

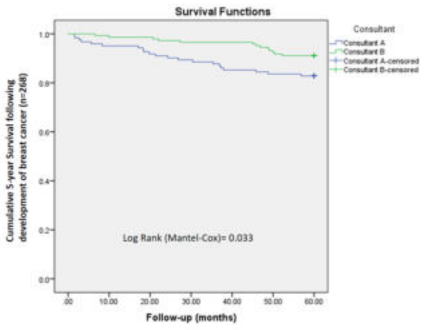

Figure 3. Net survival over time analysis of all female patients diagnosed with breast cancer.

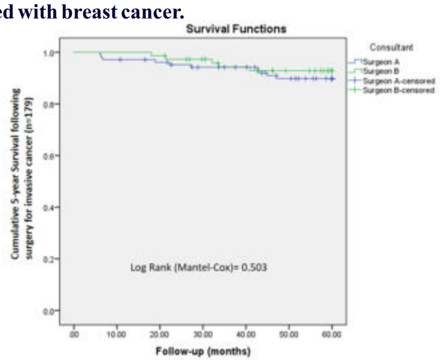

Figure 4. Kaplan-Meier curve showing net survival amongst the patients who underwent excision of primary invasive breast cancer.

List of abbreviations:

GDP	Gross Domestic Product
TNM	Tumour, Node, Metastasis
SLNB	Sentinel Lymph Node Biopsy
ICD	International Classification of Diseases
DCIS	Ductal Carcinoma in Situ
ER/PR	Oestrogen/ Progesterone
HER2	Human Epidermal Growth Factor 2
BCS	Breast Conserving Surgery
HR	Hazard Ratio
CI	Confidence Interval
USA	United States of America

Declaration:

1. Ethics approval and consent to participate:

This study was not considered a research by the NHS and formal Research Ethics Committee review was not required, in compliance with national guidelines.

2. Consent for publication:

Consent was not required in view of the facts that this was an audit project without any patient participation entailing additional clinical intervention; or sharing of identifiable individual informations.

3. Availability of data and materials:

The data that support the findings of this study are available from the Blackpool Teaching Hospitals NHS Foundation Trust, but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are however available from the authors upon reasonable request and with permission of the Blackpool Teaching Hospitals NHS Foundation Trust.

4. Competing interests:

The authors declare that they have no competing interests.

5. Funding:

None.

6. Authors' contributions:

Each author (KP, MM, NK, DA, DD) made substantial contributions to the conception and design of the work; the acquisition, analysis and interpretation of data; and drafted the work and substantively revised it. Each author (KP, MM, NK, DA, DD) approved the submitted version and all agreed both to be personally accountable for the author's own contributions and ensured that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, were appropriately investigated, resolved, and the resolution documented in the literature.

7. Acknowledgements:

Not applicable.

8. Authors' information (optional)

None

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