



## Original article

# A prospective cohort study of the safety of breast cancer surgery during COVID-19 pandemic in the West of Scotland



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## ABSTRACT

**Introduction:** In order to minimise the risk of breast cancer patients for COVID-19 infection related morbidity and mortality prioritisation of care has utmost importance since the onset of the pandemic. However, COVID-19 related risk in patients undergoing breast cancer surgery has not been studied yet. We evaluated the safety of breast cancer surgery during COVID-19 pandemic in the West of Scotland region.

**Methods:** A prospective cohort study of patients having breast cancer surgery was carried out in a geographical region during the first eight weeks of the hospital lockdown and outcomes were compared to the regional cancer registry data of pre-COVID-19 patients of the same units (n = 1415).

**Results:** 188 operations were carried out in 179 patients. Tumour size was significantly larger in patients undergoing surgery during hospital lockdown than before (cT3–4: 16.8% vs. 7.4%; p < 0.001; pT2 – pT4: 45.5% vs. 35.6%; p = 0.002). ER negative and HER-2 positive rate was significantly higher during lockdown (ER negative: 41.3% vs. 17%, p < 0.001; HER-2 positive: 23.4% vs. 14.8%; p = 0.004). While breast conservation rate was lower during lockdown (58.6% vs. 65%; p < 0.001), level II oncoplastic conservation was significantly higher in order to reduce mastectomy rate (22.8% vs. 5.6%; p < 0.001). No immediate reconstruction was offered during lockdown. 51.2% had co-morbidity, and 7.8% developed postoperative complications in lockdown. There was no peri-operative COVID-19 infection related morbidity or mortality.

**Conclusion:** breast cancer can be safely provided during COVID-19 pandemic in selected patients.

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## 1. Introduction

Patients diagnosed with breast cancer have been facing unprecedented challenges during their treatment since the onset of SARS-CoV-2 (COVID-19) pandemic. Breast cancer specialists have struggled to maintain optimal breast cancer treatment for their

patients in the midst of potentially compromised medical resources for cancer therapy while minimising exposure of their patients to COVID-19 infection related risks [1].

Numerous professional bodies issued valuable recommendations to aid prioritisation of breast cancer care based on tumour biology and cancer stage including recommendations for the surgical treatment of breast cancer in the health care crisis [2–4]. In general, upfront surgery was recommended as a priority led by the biology and potential prognosis therefore, triple-negative and HER-2 positive disease were deemed as priority, while primary endocrine treatment was accepted to temporise surgery in luminal-A

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tumours [5].

COVID-19 infection related death has been implicated to be dependent on co-morbidities, age, and anti-cancer treatment including surgery, although the extent of contribution of these factors is confounding due to the limited evidence available [6–12]. Specifically, COVID-19 related risk in patients requiring surgery for breast cancer have been evaluated in three studies only [7,13,14]. Therefore, we evaluated the safety of breast cancer surgery during COVID-19 pandemic in a prospective observational study in the West of Scotland region during the first eight weeks of the United Kingdom national lockdown, and compared outcomes to the regional cancer registry data of pre-COVID-19 patients.

## 2. Methods

A prospective registry of patients who had surgical treatment for invasive or non-invasive breast cancer in the West of Scotland was created when lockdown was introduced by the Scottish Government on 23 March 2020. Patients entered in the first 8 weeks of the lockdown, between 23 March 2020 and 15 May 2020, were included in the analysis. Three NHS Scotland Health Boards participated in the audit, which was approved by the relevant clinical directors of the health boards.

The following parameters were collected prospectively: age, dates of diagnosis and surgery, perioperative risk factors (BMI, co-morbidities, smoking habit, ASA grade), clinical and pathological tumour size, nodal status, subtype, grade, ER and HER-2 expression, details of neoadjuvant treatment, types of breast and axillary surgery, length of hospital stay, treatment affected by COVID-19 pandemic, COVID-19 infection rates, details of postoperative complications, unplanned hospital readmission or return to operating theatre.

This prospective cohort was compared against a cohort of patients ( $n = 1415$ ) from the same region, who were diagnosed with invasive or non-invasive breast cancer between 1 January 2015 and 31 December 2015. This cohort was identified from the prospectively maintained Managed Clinical Network (MCN) database and Caldicott Guardian approval was gained previously [15]. Comparison was made of clinicopathological factors and surgical treatments between pre-COVID-19 hospital lockdown and the same units during hospital lockdown due to COVID-19 pandemic.

During lockdown all patients were screened for possible COVID-19 infection related symptoms. In cases where COVID-19 infection was clinically suspected patients were asked to self-isolate and surgery was postponed by a minimum of two weeks followed by a re-assessment of the patient. In one Health Board routine preoperative COVID-19 PCR testing was introduced four weeks after the hospital lockdown, which was performed within 72 h of the date of surgical treatment followed by self-isolation until the time of surgery. The operating hospitals were non-receiving hospitals for patients with diagnosed COVID-19 infections including Ambulatory Care and Diagnostic Centre facility or independent sector hospital procured for NHS cancer surgery. These hospitals do not have a High Dependency Unit so patients requiring emergency surgery, or those deemed as having a high anaesthetic risk were operated on in an acute receiving hospital where patients with diagnosed COVID-19 infection were being treated. Data collection and analysis was performed using Microsoft Excel 365 Software. Statistical significance (considered as  $p \geq 0.05$ ) was calculated using Mann-Whitney  $U$  test, Chi-Square test and Z-test for two proportions, as appropriate.

## 3. Results

179 patients were included in the analysis, all patients

underwent surgical treatment for invasive or non-invasive breast cancer in the West of Scotland. Three of the four NHS Scotland Health Boards in the West of Scotland participated in the audit including seven of the eleven breast surgical units of the region. These seven breast units diagnose and treat 61.2% (1415 of 2292) of all newly diagnosed breast cancers in the region yearly based on previous figures of Managed Clinical Network in Scotland (2015), hence this is a representative audit of the region.

189 surgeries were carried out in 180 patients. 5 patients had two oncological surgeries, another 4 patients returned to theatre due to postoperative complications. One patient required emergency surgery to remove an infected implant inserted 10 months earlier, who was excluded from the analysis.

Median age of the patients was 54 years (27–81). Date of diagnosis ranged between 31 July 2019 and 7 May 2020. 42 of the 179 patients were diagnosed during lockdown due to the COVID-19 pandemic. Almost two-thirds of the patients were diagnosed in the symptomatic service (64.8%), which was significantly higher compared to patients diagnosed in the symptomatic service before lockdown in this region (52.9%;  $p < 0.001$ ) (Table 1.). Breast screening had been stopped in Scotland at the start of lockdown.

Median preoperative tumour size was 25 mm (5–110). The clinical tumour size was significantly larger in patients undergoing surgery during lockdown with 28 patients (16.8%) having cT3–4 disease compared to patients operated before lockdown (vs. 154 of 1415 patients (7.4%);  $p < 0.001$ ) (Table 1). This trend is reflected in the pathological tumour size with more patients having surgery for pT2 – pT4 disease during the pandemic compared to patients treated before lockdown (45.5% vs. 35.6%;  $p = 0.002$ ). However, the rate of clinically and pathologically node positive disease were similar in patients who underwent surgery during lockdown compared to the pre-lockdown times (cN1–3: 24.9% vs. 19.1%,  $p = 0.099$ ; (y)pN1–3: 30.8% vs. 31.8%,  $p = 0.791$ ). Tumour subtypes and grade were comparable in the two groups with somewhat less patients undergoing surgery for DCIS and more patients undergoing surgery with G3 disease during the COVID-19 pandemic ( $p = 0.057$  and  $p = 0.107$ , respectively). However, a sharp difference between ER- and HER-2 expression were found in between the two groups with significantly more patients having ER negative and HER-2 positive disease in the COVID-19 group compared to patients operated before the pandemic (ER negative: 41.3% vs 17%,  $p < 0.001$ ; and HER-2 positive: 23.4% vs. 14.8%,  $p = 0.004$ ) (Table 1.).

105 (58.6%) patients had breast conservation surgery (BCS) during lockdown, of which 24 (13.4%) patients underwent level II oncoplastic breast conservation surgery comprising of 22.8% oncoplastic surgical rate of all BCSs (Table 2.). While BCS rate was higher in patients operated before the COVID-19 pandemic (65%), only 5.6% of the patients were treated with oncoplastic surgery of all patients treated with BCS (Table 2.). There was no immediate reconstruction carried out during lockdown and no significant difference was found in terms of axillary surgical procedures between the two groups of patients. Length of hospital stay during lockdown was less than 24 h in 166 cases (90.2%), and of these day-case surgery was carried out in 65 cases (35.3%). Significantly higher proportion of patients received neo-adjuvant chemotherapy in the COVID-19 group compared to the patients treated before the pandemic (30.1% vs. 10.4%;  $p < 0.001$ ).

For perioperative risk factors BMI, co-morbidities, recent smoking habit and COVID-19 infection was analysed (Table 3.). The median BMI of the patients was 26.3 (15–48), with 128 patients (71.5%) being at least overweight, of which 57 (35%) suffered from various degree of obesity (Table 3). 93 patients (51.2%) had co-morbidity, of which 29 patients (16.2%) had at least two co-morbidities documented. 27 patients (15.7%) were current smokers. Similar data for co-morbidities are not available in the

**Table 1**

Comparison of clinicopathological characteristics of patients treated during COVID-19 pandemic caused hospital lock down and outside of the pandemic in the West of Scotland.<sup>1</sup> Data was not available for 12 patients in the COVID database and 717 patients had either cT0, or primary tumour was not assessed in the MCN database.<sup>2</sup> Data was not available for 11 patients in the COVID database and 26 patients lymph nodes were not assessed or recorded in the MCN database.<sup>3</sup> Final pathology is awaiting in 7 patients in the COVID database and primary tumour subtype was not assessable or recorded in 19 patients in the MCN database.<sup>4</sup> Grade not assessable or not applicable in 218 patients in the MCN database. Grade, ER status and HER-2 status were determined in invasive cancer only.

Clinicopathological characteristics		COVID-19 database		MCN database		P value
		No. of patients (%)		No. of patients (%)		
Presentation	symptomatic	116	64.8%	749	52.9%	<0.001 CS
	screener	57	31.8%	469	33.1%	
	other	6	3.3%	197	13.9%	
cT <sup>1</sup>	cTis	7	4.2%	132	6.3%	<0.001 CS
	cT1	57	34.1%	685	32.7%	
	cT2	75	44.9%	1121	53.6%	
	cT3–4	28	16.8%	154	7.4%	
cN <sup>2</sup>	cN0	127	75.1%	1125	80.9%	0.099 (NS)
	cN1–3	41	24.9%	265	19.1%	
	Tumour subtype <sup>3</sup>					
DCIS/LCIS	8	4.7%	116	8.3%		
Ductal	126	73.7%	988	70.8%		
Lobular	22	12.7%	152	10.9%		
Mixed	3	1.7%	16	1.1%		
Mucinous	2	1.2%	22	1.5%		
Tubular	2	1.2%	15	1.1%		
Papillary	2	1.2%	5	0.3%		
Other	5	2.9%	71	5.1%		
Inflammatory	1	0.6%	11	0.8%		
(y)pT	yPt0	10	5.9%	N/A	N/A	0.002 CS
	(y)pTis	11	6.5%	116	10.1%	
	(y)pT1	71	42%	619	54.1%	
	(y)pT2	57	33.7%	344	30.1%	
	(y)pT3 – T4	20	11.8%	64	5.6%	
Grade <sup>4</sup>	G1	11	6.8%	96	9.1%	0.107 (NS) CS
	G2	70	43.2%	522	49.5%	
	G3	81	50%	436	41.3%	
ER expression <sup>4</sup>	negative	67	41.3%	217	17%	<0.001 = 0.004
HER-2 expression <sup>4</sup>	positive	38	23.4%	188	14.8%	
(y)pN <sup>4</sup>	(y)pN0	112	69.1%	711	68.2%	= 0.791 (NS)
	(y)pN1	36	22.2%	253	24.2%	
	pN2	8	4.9%	53	5.1%	
	pN3	6	3.7%	26	2.5%	

MCN database, hence a direct comparison could not have been carried out.

Altogether 14 patients (7.8%) developed postoperative complications, of which 6 patients (3.3%) had major complication requiring in-hospital treatment. 4 patients returned to theatre for complications including evacuation of haematoma and washout of infected seroma (Table 3.). Two of these four cases were carried out in an acute receiving hospital with patients treated with COVID-19 infection. A further two patients required transfer to the acute receiving hospital. One of them developed postoperative hypoxia, while the other patient had delirium. Of the elective cases, four patients with significant co-morbidities were operated on in acute receiving site (one unilateral therapeutic mammoplasty and three mastectomies).

Patient management was affected by COVID-19 pandemic in 78 patients (43.6%) overall (Table 4.). 40 patients would have been suitable for immediate postmastectomy breast reconstruction, which comprised of 62.5% of all patients treated with mastectomy during COVID-19 lockdown. Of the six patients who had unilateral therapeutic mammoplasty through a “Wise” pattern incision, five would have had immediate contralateral symmetrisation outside the pandemic. 28 patients had their neo-adjuvant chemotherapy interrupted due the pandemic, which comprised of 51.8% of all patients having surgery after neo-adjuvant chemotherapy during the pandemic. Conversely, 12 patients went straight to surgery who would have been offered neoadjuvant chemotherapy outside COVID-19. In 14 patients (7.8%) both the surgical and adjuvant treatments were affected by the pandemic (Table 4.).

COVID-19 infection was suspected in five patients altogether. In two patients the preoperative imaging raised suspicion of COVID-19 infection, and surgery was delayed by two weeks but patients were not tested. In further three patients postoperative COVID-19 infection was suspected. These three patients all subsequently tested negative, although one of them required transfer to an acute receiving hospital due to hypoxia. There was one patient who tested positive on routine preoperative COVID-19 testing, whose surgery was also delayed. There was no mortality and no peri-operative COVID-19 infection related morbidity detected in this cohort of patients.

**4. Discussion**

Our study of 179 patients undergoing breast cancer surgery in the West of Scotland region during the COVID-19 pandemic demonstrates that selected surgery for breast cancer surgery can be safely delivered. Initial data suggested that cancer patients receiving anti-cancer treatment have a higher mortality rate if they develop COVID-19 infection. A retrospective analysis by Zhan et al. of 28 patients from Wuhan, China showed a 28.6% mortality rate, and having the last anti-cancer treatment within 14 days of the infection significantly increased the risk of mortality from COVID-19 infection [12]. Similarly, a nationwide analysis by Liang et al. showing similar data based on the extraction of data from 18 cancer patients from 1590 patient with COVID-19 infection [16]. However more recent data by Lee et al. from the UK Coronavirus Cancer Monitoring Project (UKCCMP), which involved 800 cancer patients

**Table 2**

Comparison of breast cancer surgeries during COVID-19 pandemic caused hospital lock down and outside of the pandemic in the West of Scotland. <sup>1</sup>In 7 patients contralateral symmetrising reduction was carried out simultaneously. <sup>2</sup>In one patient bilateral mastectomy was carried out. LICAP = lateral intercostal perforator flap. <sup>3</sup>In 7 patients the WLE was carried out before the hospital lock down, while in another patients both the wide and the re-excision were done during lock down. <sup>4</sup>In the breast 220 patients and in the axilla 344 patients did not receive any/require surgery or refused treatment or data not recorded. TM = therapeutic mammoplasty with breast reduction technique from “wise” patter incision. ANC = axillary node clearance. SLNB = sentinel node biopsy. Sym. red. = symmetrising reduction. Round bl. = round block technique. LICAP = lateral intercostal perforator flap. AICAP = anterior intercostal perforator flap. In 2 cases axillary surgery was carried out only. In 28 cases no axillary surgery was carried out.

Surgical technique		COVID database			MCN database			p value	
		No. of cases	Per cent	Details of operations	No. of cases	No. of cases <sup>4</sup>	Per cent		
Breast surgery									
OBCS	Therapeutic mammoplasty <sup>1</sup>	13	7.7%	TM + ANC TM + SLNB TM + sym. red + SLNB	2 4 7	41	3.5%	<0.0001	
	LICAP flap reconstruction	6	3.5%	LICAP + SLNB LICAP + ANC	5 1				
	AICAP flap reconstruction	2	1.2%	AICAP + SLNB AICAP + ANC	1 1				
	Round block excision	3	1.8%	Round bl. + SLNB Round bl.	2 1				
Wide local excision		81	47.9%	WLE + SLNB WLE + ANC WLE	63 9 9	730	61.6%		
Mastectomy		64	37.9%	Mx <sup>2</sup> + ANC Mx + sampling Mx only Mx + SLNB	27 1 5 31	314	26.5%		
Mastectomy and IBR		0	0		0	100	8.4%		
Re-excisions <sup>3</sup>		13	N/A	Re-exc. Re-exc. + ANC	12 1	N/A	N/A		
Axillary surgery									= 0.05
Sentinel lymph node biopsy		113	72.4%			851	79.4%		
Axillary clearance		41	26.3%			203	18.9%		
Sampling		1	0.6%			16	14.9%		
Excision of lymph node		1	0.6%			1	0.01%		

with COVID-19 infection, demonstrated no significant effect on mortality for patients who received chemo-, immuno-, hormonal, or radiotherapy within 4 weeks of the infection [8]. Vaugnat et al. claimed the same analysing a population of 59 patients with COVID-19 infection from the 15600 patients actively treated with breast cancer at the Institut Curie Hospitals [10]. In fact, age (>70), male gender and severe comorbidities were independently associated with mortality from COVID-19 infection [8,10].

Early data of patients with COVID-19 infection undergoing elective general surgery suggested a significantly increased mortality rate up to 20.5% based on the analysis of 34 patients in Wuhan, China [9]. This preliminary finding was confirmed by a large scale international cohort study (COVIDSurg collective) including 294 patients with preoperatively confirmed COVID-19 infection from a cohort of 1128 undergoing surgery [6]. In adjusted analyses, 30-day mortality was associated with male gender, age (>70), ASA grade 3–5, malignancy, emergency and/or major surgery [6]. The COVID-19 and Cancer Consortium (CCC19) database including 928 patients with COVID-19 infection undergoing active anti-cancer treatment revealed that 30-day all-cause mortality is independently associated with age, male gender, and the number of comorbidities among others, but not with the type of anti-cancer therapy or recent surgery [7].

There is hardly any evidence however on the safety of breast cancer surgery during COVID-19 pandemic available as the number of patients who had breast cancer surgery were either single figures (Wuhan study, COVIDSurg collective) or the breast cancer specific anti-cancer treatment (CCC19 database: 191 breast cancers, UKCCMP study: 102 breast cancers) were not provided [6–9].

In terms of surgical techniques more oncoplastic breast conservations were carried out in comparison to our pre-COVID-19 practice due to immediate breast reconstruction not being offered

after mastectomy (Table 2.). Oncoplastic breast conservation surgery has been shown as a safe alternative to mastectomy and immediate breast reconstruction in selected patients based on the combined data of iBRA-2 and TeaM studies of 2916 patients [17]. Further, the Scottish audits of oncoplastic breast conservations indicate that oncoplastic surgery can widen the indications for breast conservation, and provide good oncological outcome with low complication rates in our hands, hence it can be a reasonable alternative to mastectomy with immediate reconstruction [18–21]. One unit in Italy did offer immediate breast reconstruction even during the peak of the COVID-19 pandemic as it is indicated by Fragetti et al. who reported 15 nipple-sparing mastectomies with immediate reconstruction done in 13 patients, although reconstructive techniques were not disclosed [14]. In our study the higher rate of oncoplastic breast conservation surgery was partly a consequence of declined immediate breast reconstruction due to COVID-19 risks as opposed to an elective planned argument, although it also reflects practice changes over a period of five years. Nevertheless, a very careful approach, within a framework of close collaboration between breast and reconstructive surgeons, is required to carefully select patients and reconstructive techniques to allow re-starting of immediate breast reconstructions when appropriate [2,22].

In terms of COVID-19-related risk in patients undergoing treatment for breast cancer we found six patients of the 179 who had suspected or proven COVID-19 infection perioperatively. Corsi et al. reported on 63 patients who underwent breast cancer surgery over a five-week period in one of the breast units in Pavia (Lombardy, Italy), with one patient only being diagnosed with COVID-19 infection [23]. Similarly, Fragetti et al. reported on 85 patients, who had breast cancer surgery in a four-week time period with three patients being diagnosed with COVID-19 infection preoperatively

**Table 3**

Risk factors and postoperative complications in patients operated during COVID-19 pandemic caused hospital lock down in the West of Scotland.<sup>1</sup> No data available for 4 patients.<sup>2</sup> No data available for BMI in 16 patients.<sup>3</sup> No data available in 7 patients.<sup>4</sup> No data available on 9 patients. CV = cardio-vascular. HTN = hypertension. Resp = respiratory.

	No. of patients (%)	Details of risk factors	No. of patients
Risk factors			
Co-morbidities <sup>1</sup>	93 (53.1%)	Respiratory only (asthma, COPD, bronchiectasis)	7
		CV only (HTN, DVT, AF, mitral regurg, IHD, CVA, MVR)	31
		Endocrine (DM, hypo, hyperthy)	4
		Musculo-skeletal (OA, RA)	3
		Morbid obesity	6
		Other (anaemia, chronic pain, Guillan-Barré sy, epilepsy, MS, PBC, depression, SLE, previous malignancy)	11
		GI (GORD)	6
		Combined Resp + CV	6
		Combined Resp + other	2
		Combined CV + morb obesity	1
		Combined CV + GI	2
		Combined CV + morb obesity + endocrine	1
		Combined CV + other	2
		Combined CV + GI + endocrine	1
		Combined CV + GI + endocrine + morb obese	1
		Combined CV + GI + other	1
		Combined endocrine + other	3
		Combined Resp + CV + other	1
Obesity <sup>2</sup>	57 (35%)	Obese	23
		Severe obese	24
		Morbidly	10
Current Smoker <sup>3</sup>	27 (15.7%)		
ASA II and above <sup>4</sup>	124 (69.3%)	ASA II	114
		ASA III	10
Complications			
Clavien-Dindo I	8 (4.5%)	Repeated of aspirations of seroma	1
		Infection treated with oral antibiotics	6
		Delayed wound healing	1
Clavien-Dindo II	2 (1.1%)	Postoperative hypoxia	1
		Postoperative delirium	1
Clavien-Dindo III	4 (2.2%)	Evacuation haematoma	2
		Washout of infected seroma	2

**Table 4**

Impact of COVID-19 pandemic and consequent hospital lock down on the overall management of patients. LA = local anaesthetic. GA = general anaesthetic. IBR = immediate breast reconstruction. NAC = neo-adjuvant chemotherapy. PET = primary endocrine therapy.

Impact of COVID-19 pandemic on patients' management	No. of patients	% of all patients
IBR not carried out	28	15.6%
Contralateral reduction not carried out	3	1.7%
Change to LA from GA	1	0.5%
NAC not completed	19	10.6%
NAC not completed + Contralateral reduction not carried out	2	1.1%
NAC not completed + IBR not carried out	7	3.9%
NAC not offered	7	3.9%
NAC not offered + IBR not carried out	5	2.8%
PET due to COVID-19 lockdown, surgery delayed	5	2.8%
PET due to presumed COVID-19 infection, surgery delayed	1	0.5%

and further three patients required to have two-week delay in surgery due to suspected infection [14]. These figures imply that we need to carefully select our patients and avoid operating – if possible – on those with relatively high COVID-19 mortality risk. The above mentioned three large prospective cohort studies (UKCCMP, CC19, COVIDSurg) had similar outcomes in terms of risk factors for COVID-19 related death, hence surgery should be carried out with extreme caution in patients with multiple co-morbidities in particular those who are elderly [6–8].

There is some weakness of this paper which mainly relates to the control group of patients from the MCN database. Breast surgical practice has undoubtedly changed in the last 5 years hence a more recent cohort would have been more ideal. Due to time pressure arising from the relative urge of these results during lockdown this was not available in the MCN database at the time

when the manuscript was written. Further, we did not have co-morbidity data in the MCN database so we could not make a comparison which would have been an important point of the study. Nevertheless, this study provides the strongest evidence about safety of breast cancer surgery in lockdown due to COVID-19 infection, and may provide reassurance in the future if lockdown happens again.

In conclusion, we have demonstrated that in a population in whom over 50% have co-morbidities surgery for breast cancer can be safely provided during COVID-19 pandemic in selected patients.

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