

# Impact of the COVID pandemic on study participation

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## Introduction

'Outcome Monitoring After Cardiac Surgery (OMACS)' is an observational study creating a database of all cardiac surgery patients undergoing cardiac surgery at University Hospitals Bristol and Weston NHS Trust. Complication data, blood/tissue samples and quality of life (QoL) outcomes are collected, with further linkage to routine data sources, for use in research. Following a pause to recruitment during the first wave of the COVID-19 pandemic, recruitment resumed in May 2020. We've used this dataset to investigate the influence of the pandemic on participant engagement with clinical research.

## Methods:

We compared the following in cohorts of OMACS participants undergoing cardiac surgery before the pandemic and during the pandemic:

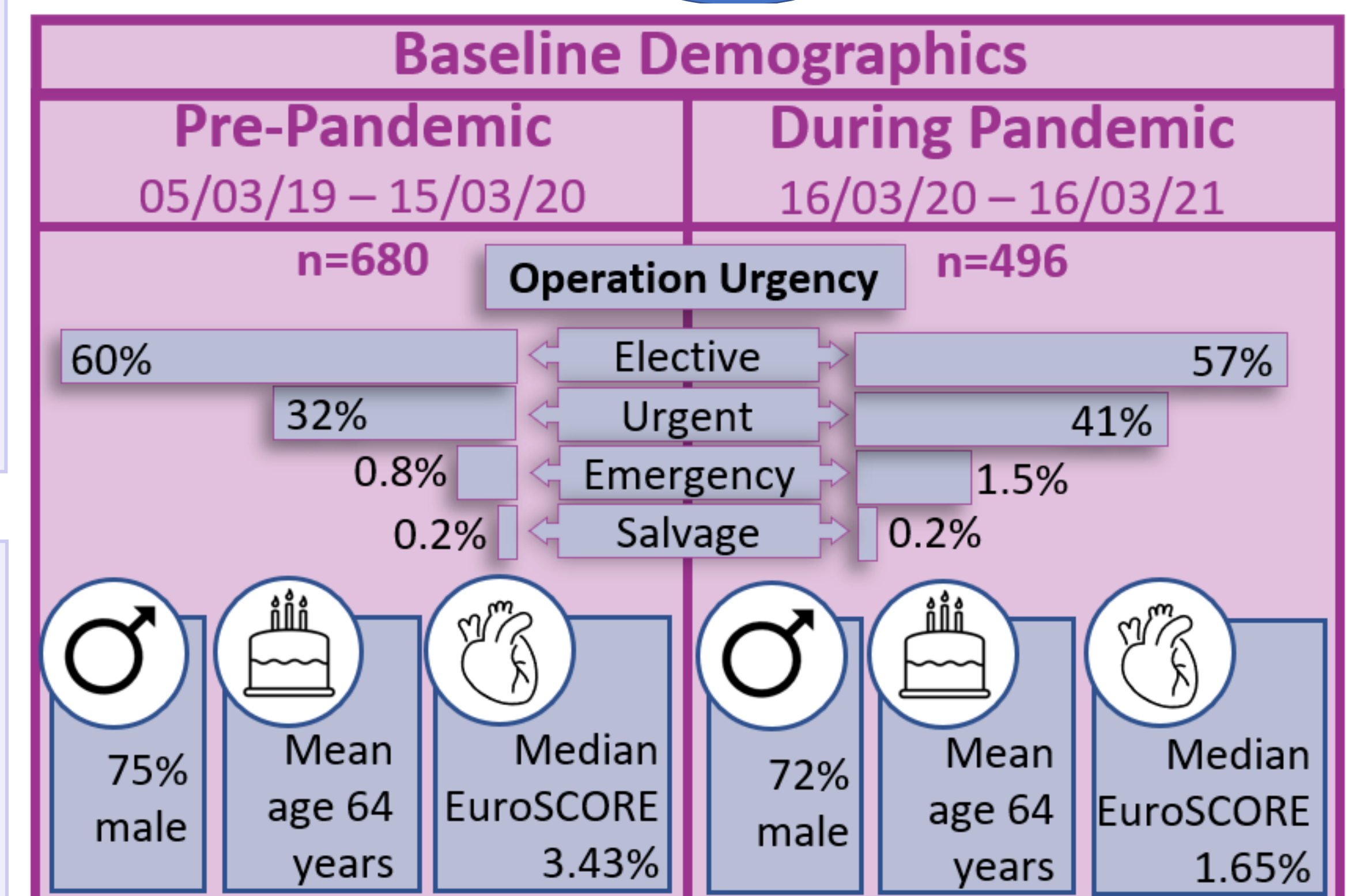
- Recruitment rate (based on date approached)
- Baseline demographics
- Study retention, based on return of 3 month QoL questionnaires
- QoL questionnaire data completeness
- QoL scores, assessed by Coronary Revascularisation Outcomes Questionnaire (CROQ) for coronary artery bypass grafting (CABG) or SF12 for all other procedures

## Results:

During the pandemic slightly more patients underwent urgent operations. Patients were healthier, evidenced by lower median EuroSCORE (a measure of risk of mortality after heart surgery). Pre-operative factors that contributed to the difference in EuroSCORE were:

- Proportionally fewer patients had COPD (6% vs 10%) and extracardiac arteriopathy (8% vs 12%) during the pandemic
- More patients had good pre-operative ventricular function (82% vs 77%).

Recruitment rate: 73% pre-pandemic vs. 66% during pandemic



Retention rate (return of 3 month QoL questionnaires): 67% pre-pandemic vs. 73% during pandemic

7. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time    Most of the time    Some of the time    A little of the time    None of the time

4. This question asks about activities which you might do during a typical day. During the past 4 weeks, has your heart condition limited you in your usual daily activities? Please indicate whether your heart condition limits you a lot, limits you a little, or does not limit you at all in the activities listed below. (Please tick one box on each line.)

ACTIVITIES	Yes, limited a lot	Yes, limited a little	No, not limited at all
Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Lifting or carrying heavy objects?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Climbing stairs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5. This question asks about the impact of your heart condition on your family and friends and the extent to which it has interfered with your social activities. During the past 4 weeks, how often have you experienced the following as a result of your heart condition? (Please tick one box on each line.)

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Feeling restricted in your social activities (like visiting with friends, relatives, etc.)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Feeling lonely?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. This question asks about your feelings about your heart condition. During the past 4 weeks, how often have you felt: (Please tick one box on each line.)

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Worried about your heart condition?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Worried about doing too much or over-doing it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Worried that you might have a heart attack or die suddenly?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## Quality of Life

### QoL Data completeness:

Questions pertaining to social activities and emotional wellbeing were left blank more often during the pandemic.

- SF12 Question 7: 2% had missing data pre-pandemic compared to 6% during the pandemic.
- CROQ questions 4,5,6 and 8: ~1% with missing data for these questions pre-pandemic compared to ~4% during the pandemic.

### QoL Scores:

The majority of derived QoL scores were similar across the cohorts. CROQ satisfaction scores during the pandemic were slightly lower than pre-pandemic (77.2 during the pandemic vs 83.3 pre-pandemic). SF12 scores revealed more participants reported physical or emotional problems interfered with social activities all/most of the time during the pandemic (17% compared to 8% pre-pandemic). Conversely, more participants reported this never interfered with social activities during the pandemic (48% compared to 42%).

## Discussion:

Recruitment to OMACS was lower during the pandemic but overall remained high, this maybe because OMACS involves minimal active participation. However, it appears those who did consent were more engaged as retention was higher. The impact of the pandemic on recruitment to interventional studies with higher participant burden may be larger.

EuroSCORE indicated that patients operated on during the pandemic were healthier, which may affect operation outcomes, and this is being further investigated.

QoL questionnaire missing data is lower than anticipated given the restrictions on social activities during the lockdowns, however participants may have interpreted and answered questions differently during these periods. Trialists should consider these points when analysing QoL responses

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