

The COVID-19 pandemic as experienced by adults with congenital heart disease from Belgium, Norway, and South Korea: impact on life domains, patient-reported outcomes, and experiences with care

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Aims

The coronavirus disease-2019 (COVID-19) pandemic poses significant challenges to many groups within societies, and especially for people with chronic health conditions. It is, however, unknown whether and how the pandemic has thus far affected the physical and mental health of patient populations. Therefore, we investigated how the pandemic affected the lives of adults with congenital heart disease (CHD), compared pre- and peri-pandemic patient-reported outcome measures (PROMs) and a patient-reported experience measure (PREM), and investigated whether having had COVID-19 impacted pre-/peri-pandemic differences of the PROMs and PREM.

Methods and results

As part of the ongoing APPROACH-IS II project, we longitudinally surveyed 716 adults with CHD from Belgium, Norway, and South Korea. Pre-pandemic measures were administered from August 2019 to February 2020 and the peri-pandemic surveys were completed September 2020–April 2021. The majority of patients indicated that their social lives (80%), mental health (58%), and professional lives/education (51%) were negatively impacted by the pandemic. Patients felt worried (65%), were afraid (55%), reported the pandemic felt ‘close’ to them (53%), and were stressed (52%). However, differences between pre- and peri-pandemic scores on the PROMs and PREM were negligibly small (Cohen’s $d < 0.20$). Across measures, 5.8–15.8% of patients demonstrated changes (improved or worsened scores) that exceeded the minimal clinically important difference. There were no difference-in-differences for PROMs and PREM between patients who did vs. did not have COVID-19.

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Conclusions

Although the COVID-19 pandemic has been disruptive in many ways, pre- to peri-pandemic changes in PROMs and PREM of adults with CHD were negligibly small.

Keywords

COVID-19 • Pandemic • Patient-reported outcomes • Heart defect congenital • Quality of life • Depression

Implications for practice

- The coronavirus disease-2019 (COVID-19) pandemic has impacted on patients with congenital heart disease in various ways, both negatively as positively.
- Knowledge of the evolution of patient-reported outcomes and experiences from the pre- to peri-pandemic status may assist clinicians to understand the impact of the COVID-19 pandemic on cardiac patients.
- Patient-reported outcomes and experiences measured after the acute phase of the COVID-19 pandemic largely represent the baseline status of patients.

Introduction

The emergence of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus in humans resulted in a global coronavirus disease-2019 (COVID-19) pandemic. To keep transmissions as low as possible and to flatten the curve of infections, numerous countries implemented major public health measures, such as physical distancing, closure of public transport, curfews, and even lockdowns.¹ In some countries/regions, healthcare systems were flooded and demand exceeded existing capacity. The imposed measures and the unprecedented situation yielded a social disconnectedness for most people and had an impact on the physical and mental health of the general population.²⁻⁴

For people with chronic conditions, the COVID-19 pandemic posed several additional challenges. Given their underlying morbidity, they were presumed to be more vulnerable for adverse events if infected. Even patients who were not exposed to or infected with the virus experienced changes in healthcare access. For many, medical follow-up was temporarily halted⁵ and in-person visits were replaced by telephone or video consultations.^{6,7} Pandemic-related interruptions in care and other challenges may have contributed to poorer mental health outcomes that have been observed in people with chronic diseases.⁸

Congenital heart disease (CHD) is an example of a chronic lifelong condition. An umbrella term used to encompass dozens of types of heart defects, CHD occurs in 9.4 per 1000 newborns⁹ and 90% of patients now reach adulthood in higher-resourced countries.¹⁰ As adults with CHD are not cured and those with more complex forms of the disease face morbidity and premature mortality in adulthood, the risk of COVID-19 was concerning to CHD care teams.^{11,12} At the first surge of the pandemic, cardiac surgery and in-person consultations were often postponed and replaced by remote follow-up.¹³ In a large international study of over 1000 adults with CHD and COVID-19, 6.4% of patients required intensive care and the case fatality rate was 2.3%.¹² With regard to psychological impact, 42% of a predominantly American sample of surveyed adults with CHD reported clinically significant psychological stress in the early months of the pandemic.¹³ Among Greek patients, about 75% experienced a

moderate to severe impact on their mood.¹⁴ The possibility of inter-country variation in psychological impact of the first wave has been suggested.¹³

It is, however, unknown to what extent the pandemic impacted the physical and mental health of adults with CHD. To the best of our knowledge, intra-individual comparisons of patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs) from a pre-pandemic to the peri-pandemic state have not yet been published. Furthermore, it is important to conduct such investigations in an international context. Therefore, the aims of the present study were (i) to evaluate how adults with CHD from Belgium, Norway, and South Korea experienced the impact of the pandemic; (ii) to compare PROMs and a PREM administered pre- and peri-pandemic; and (iii) to investigate whether having had COVID-19 was related to pre-/peri-pandemic differences of PROMs and a PREM.

Methods

Study population

The present study is part of the ongoing Assessment of Patterns of Patient-Reported Outcomes in Adults with Congenital Heart disease—International Study II (APPROACH-IS II), which is a global research project conducted in more than 60 Adult Congenital Heart Disease (ACHD) centres worldwide. APPROACH-IS II is a sequel study of the first APPROACH-IS.¹⁵ Patients are eligible for inclusion in APPROACH-IS II if they meet the following criteria: (i) having CHD; (ii) aged 18 years or older at the moment of study inclusion; (iii) diagnosed before the age of 10 years; (iv) in follow-up at an adult CHD centre or included in a national/regional registry; and (v) having the physical, cognitive, and language abilities required to complete self-report questionnaires. Patients are excluded if they had prior heart transplantation. APPROACH-IS II data collection is scheduled to be finished by mid 2022.

Between August 2019 and February 2020, 873 patients were enrolled in three of the participating centres: Leuven (Belgium), Oslo (Norway), and Seoul (South Korea). Completion of PROMs and a PREM at this time constitutes the pre-pandemic data. Because of the global surge of the SARS-CoV-2 virus, the project was paused from March 2020 until June

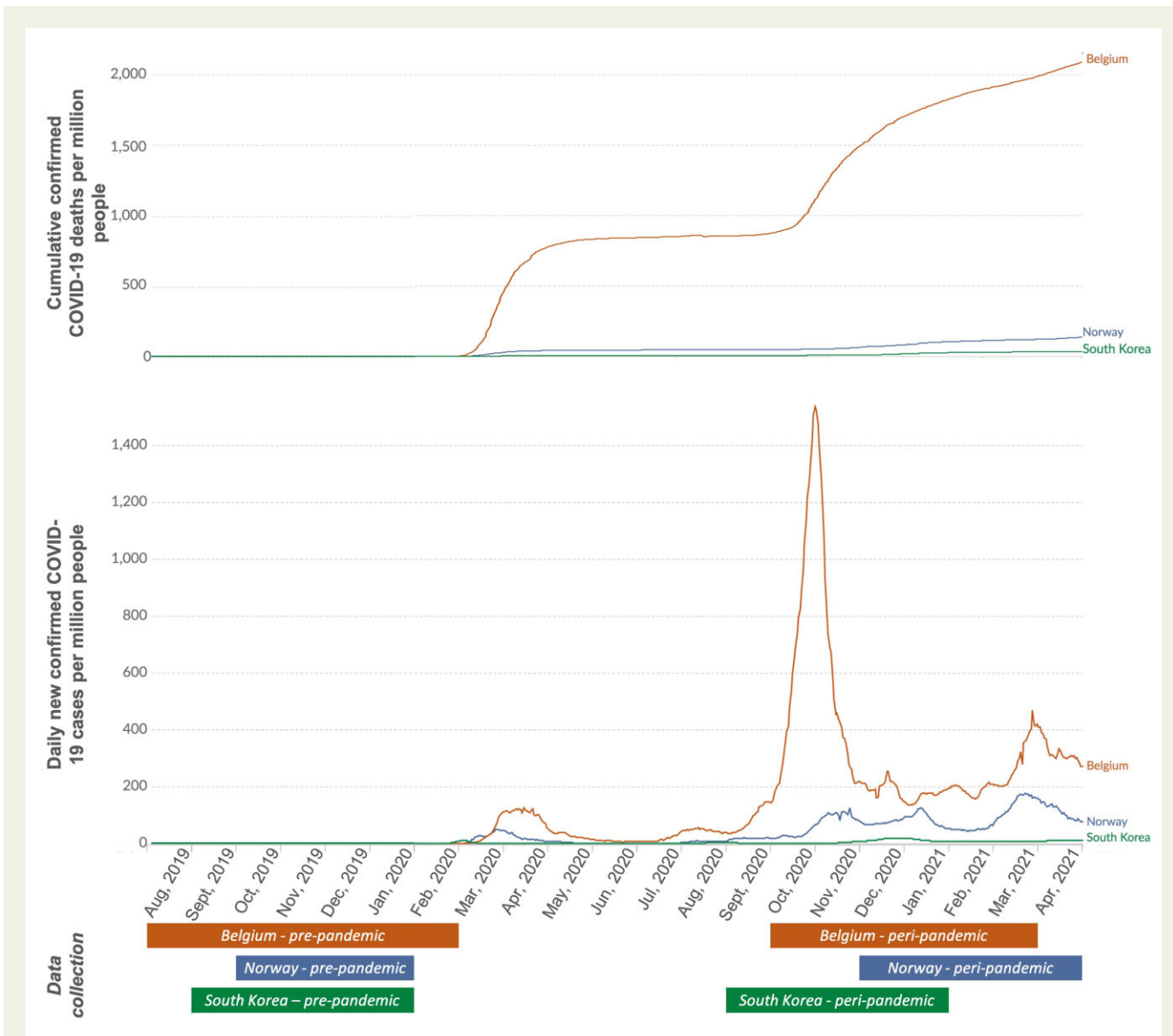


Figure 1 Evolution of the pandemic and data collection in Belgium, Norway, and South Korea. Derived from OurWorldInData.org¹⁶

2020.¹⁷ Indeed, local outbreaks and lockdowns, a shift in care priorities, reduced outpatient visits, and modified research operations made it impossible for most centres to enroll patients. Furthermore, it was hypothesized that the stress of the pandemic would bias patients' PROs and PREMs thus reducing generalizability of study findings. As of July 2020, some centres slowly resumed patient recruitment as allowed by institutional policies, whereas centres located in countries with high infection and mortality rates tended to wait until early-mid 2021 to resume or initiate data collection.

To be able to make pre- vs. peri-pandemic comparisons, we invited the 873 patients from the centres in Belgium, Norway, and South Korea to repeat completion of many of the PROMs and PREM that were originally administered to them. Between September 2020 and April 2021, 716 patients (response rate 82%) agreed to complete a second set of PROMs and PREM as well as a survey with COVID-19-specific questions. *Figure 1* reflects the pandemic evolution and the data collection waves in the three countries.

The study complies with the Declaration of Helsinki. APPROACH-IS II and the additional peri-pandemic data collection was approved by the institutional review board of the University Hospitals Leuven/KU Leuven Belgium (the coordinating centre) as well as the local institutional review boards of participating centres. All participants provided written informed consent. The study protocol of APPROACH-IS II is recorded at ClinicalTrials.gov: NCT04902768.

Measures

Demographic characteristics were captured using a self-report form. The anatomical complexity and physiological status (ACHD-AP classification)¹⁸ and the New York Heart Association (NYHA)¹⁹ class were obtained through medical chart review. These variables were collected pre-pandemic.

Patient-reported outcome measures included in this analysis were (i) perceived health status using a 12-item shortened version of the RAND-36²⁰ and Linear Analog Scale²¹; (ii) depressive symptoms using the

Patient Health Questionnaire 8 (PHQ-8)²²; (iii) anxiety using the Generalized Anxiety Disorder (GAD-7)²³; (iv) quality of life using a Linear Analog Scale²¹; (v) stigma using the Stigma Scale for Chronic Illness (SSCI-8)²⁴; (vi) illness identity using the Illness Identity Questionnaire (IIQ)²⁵; (vii) empowerment using the Gothenburg Empowerment Scale (GES) derived from the Gothenburg Young Persons Empowerment Scale²⁶; (viii) perceived social support using the Multidimensional Scale of Perceived Social Support (MSPSS)²⁷; parental involvement using adapted items from the MSPSS; and concerns about future health using a numeric rating scale. The PREM included in this study was the Modified Health Care Climate Questionnaire (HCCQ).²⁸ All measures were selected based on their psychometric properties and the availability in the required languages. The PROMs and PREM were collected pre- and peri-pandemic. Expanded definitions of the outcomes in APPROACH-IS II, as well as the interpretation of scores for the individual questionnaires, are provided in [Supplementary material online, Table S1](#).

The second set of measures (administered peri-pandemic) included a pandemic impact survey developed by the research team, based upon the WHO's survey tool regarding behavioural insights on COVID-19.²⁹ Survey items pertained to the exposure of the patients and their relatives to COVID-19, the impact of the pandemic on their lives, and individual experiences with the pandemic.

Survey data collection procedure

Centres in Belgium, Norway, and South Korea used the same data collection procedure for the initial set of (pre-pandemic) surveys. Specifically, they approached eligible patients consecutively at outpatient clinic for adults with CHD; patients completed surveys at the clinic or could take them home and return them in an addressed prestamped envelope. For peri-pandemic survey administration, South Korea used this same approach, whereas patients in Belgium and Norway could choose between pen and paper or online versions of the questionnaires.

Statistical analysis

Categorical variables are presented as absolute numbers and percentages. Continuous PROM and PREM data are presented as means and standard deviations. To compare the pre- and peri-pandemic scores, we used a paired *t*-test. To express the magnitude of the difference between the pre- and peri-pandemic state, we calculated standardized effect sizes (Cohen's *d*). The following cut-off values for Cohen's *d* were used: 0.2 to 0.5 indicative of a small effect; >0.5 to 0.8 a moderate effect; and >0.8 a large effect.³⁰ Furthermore, minimal clinically important differences (MCIDs) for all scales were calculated using a distribution-based method: one standard error of measurement.³¹ Subsequently, we computed the proportion of patients that had a decrease or increase of scores higher than the MCID. To investigate whether differences in PROMs and PREM were different for patients who had vs. had not had COVID-19, we calculated the pre-/peri-pandemic difference (peri-pandemic status minus pre-pandemic status) and performed an independent samples *t*-test with diagnosis of COVID-19 (confirmed by test or presumed) as grouping variable. Data analysis was performed using IBM SPSS Statistics for Windows, version 25 (IBM Corp., Armonk, NY, USA). Tests were two-tailed and $P < 0.05$ was used as level of significance.

Results

Sample characteristics

The sample comprised 418 patients from Belgium, 208 from South Korea, and 90 from Norway. The 716 patients whom were enrolled in the present study had a median age of 28 years and

51.3% were women ([Table 1](#)). Fifty-four percent of patients had moderately complex CHD and 31.6% had a CHD of great complexity. Half of the sample was in physiological stage B, and 58.7% was in NYHA class I.

Overall, 11.1% of the patients reported they had been diagnosed with COVID-19. More specifically, 3.2% of the patients had a COVID-19 diagnosis confirmed by testing, and 7.9% were presumed based upon symptoms but not confirmed by test ([Table 2](#)). Forty percent of patients indicated that someone close to them had contracted COVID-19, most often a close friend, a colleague or a family member with whom they did not live. A detailed description of patient characteristics and exposure to COVID-19 for the total sample and per country is presented in [Tables 1 and 2](#).

Impact of the pandemic

The pandemic had a predominantly negative impact on the lives of patients. Overall, 61.2% of patients reported a negative impact on their overall life, and 9.8% reported a positive impact ([Figure 2](#)). Domains that were most often negatively impacted were social lives (79.8%), mental health (58.2%), and professional lives/education (50.9%). Regarding physical health and family life, 14.3% and 19.2% of patients reported a positive impact, respectively. For the majority of patients, the pandemic did not have any impact on their financial situation or spiritual life.

More than half of the patients stated that the pandemic made them feel worried (64.5%), afraid (55.0%), that it felt 'close' to them (53.3%), and that it made them feel stressed (50.8%) ([Figure 3](#)). Less than half of patients felt more isolated (47.8%), lonely (41.5%), depressed (37.5%), or helpless (34.2%) as a result of the pandemic.

Patient-reported outcome measures and patient-reported experience measure before and during the pandemic

The pre- and peri-pandemic scores on the PROMs and PREM are shown in [Table 3](#). Paired *t*-tests indicated that there were statistically significant differences between the two timepoints for mental health, stigma, rejection, enrichment, social support by family, and support by healthcare providers. However, the effect sizes for these differences were all smaller than 0.2. This means that the pre-/peri-pandemic differences were negligible ([Table 3](#)). Effect sizes at country level showed that patients from South Korea had a slightly higher perception of stigma ($d = 0.27$) and rejection ($d = 0.37$) and patients from Norway had moderately less concerns about future health during the pandemic ($d = -0.51$) ([Supplementary material online, Table S2](#)).

The MCID for the questionnaires used in this study ranged from 0.37 for the social support total score to 8.25 for the mental component summary. Across PROMs and the PREM, 5.8–15.8% of patients demonstrated changes (improved or worsened scores) that exceeded the MCID ([Table 3](#)). More specifically, 5.8–15.8% of patients had improvements in measures across the timepoints, and 7.4–14.0% of patients had worsening outcomes from the pre- to peri-pandemic measurement. In 73.2–86.1% of the patients, changes were below the MCID threshold.

We did not detect a difference-in-differences for PROMs and PREM between patients who had vs. had not received a COVID-19 diagnosis ([Table 3](#)).

Table 1 Demographic and clinical characteristics

| | Total sample (n = 716) | Belgium (n = 418) | Norway (n = 90) | South Korea (n = 208) |
|---------------------------------|------------------------|-------------------|-----------------|-----------------------|
| Median age at inclusion (years) | 28 (IQR 25–41) | 27 (IQR 25–36) | 41 (IQR 30–51) | 29 (IQR 22–43) |
| Sex: women | 366/713 (51.3%) | 207/418 (49.5%) | 55/89 (61.8%) | 104/206 (50.5%) |
| Anatomical complexity | | | | |
| Simple | 99/711 (13.9%) | 83/418 (19.9%) | 6/86 (7.0%) | 10/207 (4.8%) |
| Moderate | 387/711 (54.4%) | 260/418 (62.2%) | 49/86 (57.0%) | 78/207 (37.7%) |
| Complex | 225/711 (31.6%) | 75/418 (17.9%) | 31/86 (36.0%) | 119/207 (57.5%) |
| Physiological stage | | | | |
| Stage A | 95/714 (13.3%) | 66/417 (15.8%) | 27/89 (30.3%) | 2/208 (1.0%) |
| Stage B | 362/714 (50.7%) | 136/417 (32.6%) | 42/89 (47.2%) | 184/208 (88.5%) |
| Stage C | 237/714 (33.2%) | 195/417 (46.8%) | 20/89 (22.5%) | 22/208 (10.6%) |
| Stage D | 20/714 (2.8%) | 20/417 (4.8%) | 0/89 (0.0%) | 0/208 (0.0%) |
| NYHA classification | | | | |
| Class I | 419/714 (58.7%) | 369/417 (88.5%) | 46/89 (51.7%) | 4/208 (1.9%) |
| Class II | 266/714 (37.3%) | 42/417 (10.1%) | 34/89 (38.2%) | 190/208 (91.3%) |
| Class III | 29/714 (4.1%) | 6/417 (1.4%) | 9/89 (10.1%) | 14/208 (6.7%) |
| Class IV | 0/714 (0.0%) | 0/417 (0.0%) | 0/89 (0.0%) | 0/208 (0.0%) |

IQR, interquartile range; NYHA, New York Heart Association.

Table 2 Exposure to coronavirus in adults with congenital heart disease

| | Total sample | Belgium | Norway | South Korea |
|---|-----------------|-----------------|---------------|----------------|
| Are you, or have you been, diagnosed with the coronavirus? | | | | |
| Yes, I was tested and the test result was positive | 23/711 (3.2%) | 20/415 (4.8%) | 2/88 (2.3%) | 1/208 (0.5%) |
| Yes, suspected but not confirmed by a test | 56/711 (7.9%) | 15/415 (3.6%) | 1/88 (1.1%) | 40/208 (19.2%) |
| No, I was tested and the test result was negative | 294/711 (41.4%) | 152/415 (36.6%) | 48/88 (54.5%) | 94/208 (45.2%) |
| No and I was not tested | 338/711 (47.5%) | 228/415 (54.9%) | 37/88 (42.0%) | 73/208 (35.1%) |
| Has somebody close to you been diagnosed with the coronavirus? | | | | |
| Yes | 282/707 (39.9%) | 193/411 (47.0%) | 17/88 (19.3%) | 72/208 (34.6%) |
| Who has been diagnosed with the coronavirus? (not mutually exclusive) | | | | |
| Somebody in my household | 64/282 (22.7%) | 32/193 (16.6%) | 4/17 (23.5%) | 28/72 (38.9%) |
| Family member/partner with whom I do not live | 87/282 (30.9%) | 63/193 (32.6%) | 7/17 (41.2%) | 17/72 (23.6%) |
| Close friend | 100 (35.5%) | 65/193 (33.7%) | 5/17 (29.4%) | 30/72 (41.7%) |
| Colleague | 98/282 (34.8%) | 83/193 (43.0%) | 3/17 (17.6%) | 12/72 (16.7%) |
| Neighbour | 40/282 (14.2%) | 17/193 (8.8%) | 1/17 (5.9%) | 22/72 (30.6%) |
| Other | 31/282 (11.0%) | 28/193 (14.5%) | 2/17 (11.8%) | 1/72 (1.4%) |

Discussion

In the present longitudinal study, based upon a survey specifically asking about the impact of the COVID-19 pandemic, adults with CHD from Belgium, Norway, and South Korea experienced adverse outcomes in their social lives, mental health, and professional lives/education. Six to 12 months into the pandemic, patients often felt worried, afraid, and stressed. The pandemic felt close to a large

proportion of patients, which is unsurprising because 40% had someone close to them contract COVID-19. However, there were also positive outcomes of the pandemic for some patients. Specifically, one in five patients reported a positive impact on family life and one in six experienced benefits for their physical health. At the group level, effect sizes were negligible for differences in PROMs and the PROM scores from the pre- to peri-pandemic time period. In 73–86% of the patients, changes remained within MCID boundaries.

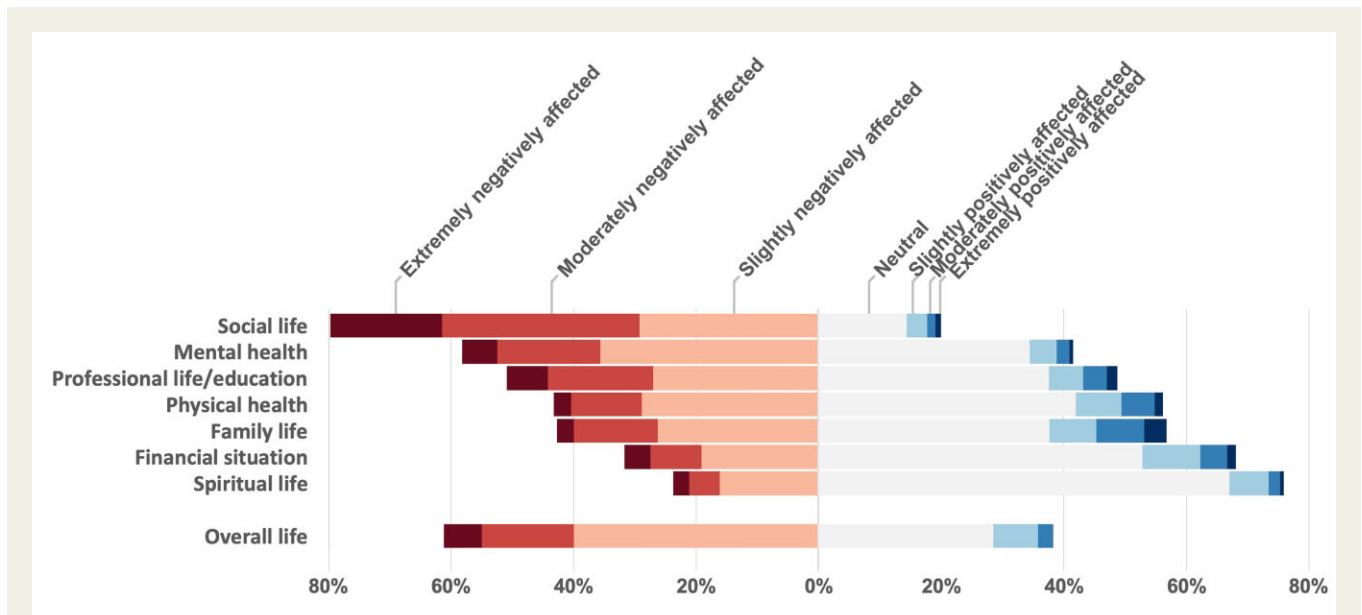


Figure 2 Life domains that are affected by the pandemic in adults with congenital heart disease.

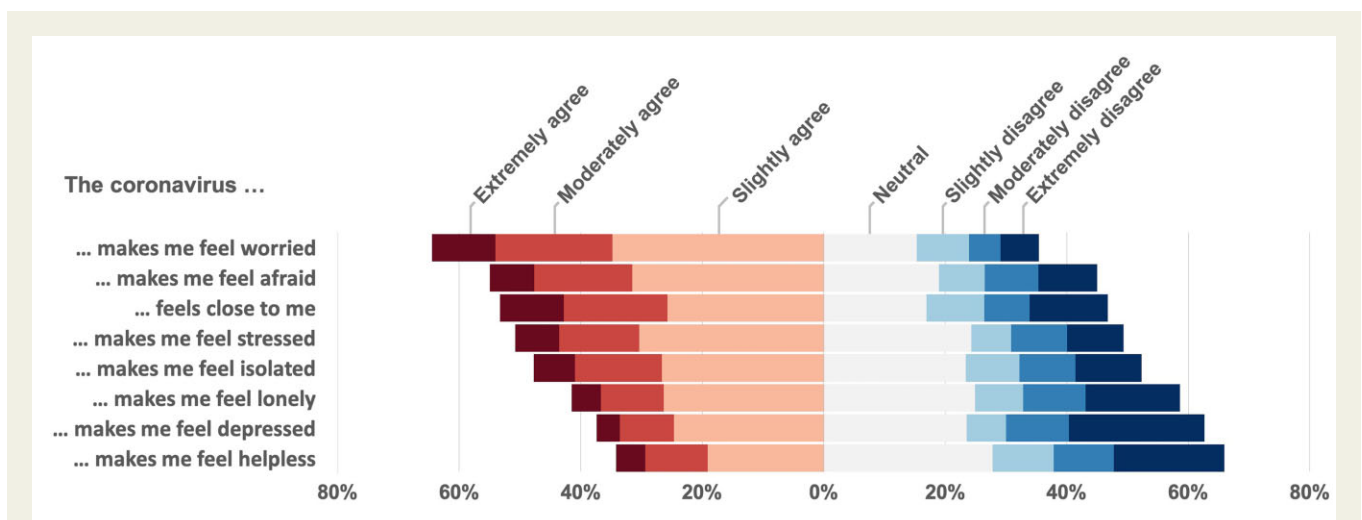


Figure 3 How adults with congenital heart disease feel about the coronavirus.

Studies in patients with CHD that were conducted during the first lockdown (March–May 2020) have been published. In a predominantly American sample of adults with CHD, 42% reported significant levels of psychological stress, which was unrelated to type of heart defect.¹³ In a Spanish cohort of patients with CHD, moderate to severe depression was found in 14% of the patients during the quarantine, and patients taking anxiolytic/antidepressant medications and/or had psychological/psychiatric evaluation in the previous year were most vulnerable.³² In a study of Greek adults with CHD, 18.9% reported that their emotional state was severely impacted during lockdown, and 51.6% said that it had a moderate impact on their mood.¹⁴ Public health lockdowns also impacted physical health. For example, British adults with CHD reported lower levels of physical

activity during lockdown compared to the pre-pandemic era.³³ Commonly-reported reasons included fear of COVID-19, loss of motivation and closing of gym/fitness centre.³³ In a cohort of Canadian children with CHD, markedly lower step counts were observed when the first lockdown occurred and schools were suspended.³⁴ Decreases in physical activities may explain why adults with CHD from Switzerland reported lower physical health-related quality of life than healthy controls during the first wave of the pandemic, whereas no difference was observed in the pre-pandemic period.³⁵

Although statistically significant differences were observed in several studies, upon closer review the effects appear rather small. For instance, in a general Swedish population, it was found that the phys-

Table 3 Pre- and peri-pandemic patient-reported outcomes and experience in adults with congenital heart disease

| | Pre-pandemic, mean (SD) | Peri-pandemic, mean (SD) | Pre-/peri-pandemic comparison t (P-value) [§] | Effect size (d) | MCID | Decrease ^a | Increase ^a | COVID19/no COVID19 comparison t (P-value) [¶] |
|-----------------------------------|-------------------------|--------------------------|--|-----------------|------|-----------------------|-----------------------|--|
| PROMs | | | | | | | | |
| Perceived physical health (PCS) | 75.1 (20.1) | 75.5 (20.3) | -0.92 (0.360) | 0.02 | 6.61 | 9.6% | 10.5% ^b | -1.20 (0.232) |
| Perceived mental health (MCS) | 68.0 (18.0) | 66.2 (18.7) | 3.18 (0.002) | -0.10 | 8.25 | 14.0% | 10.5% ^b | 1.08 (0.283) |
| Perceived overall health (LAS) | 69.2 (18.0) | 69.3 (17.6) | -0.22 (0.823) | 0.008 | 8.06 | 10.8% | 10.1% ^b | 0.27 (0.790) |
| Depressive symptoms | 5.2 (4.4) | 5.2 (4.4) | 0.06 (0.954) | -0.005 | 1.75 | 12.0% ^c | 12.2% | 0.02 (0.984) |
| Anxiety symptoms | 4.4 (4.1) | 4.4 (4.2) | -0.29 (0.769) | 0.004 | 1.79 | 11.1% ^c | 11.3% | -0.09 (0.927) |
| Quality of life | 71.0 (17.0) | 70.5 (16.3) | 1.35 (0.177) | -0.03 | 7.56 | 11.9% | 8.5% ^b | -0.03 (0.980) |
| Stigma | 10.1 (3.0) | 10.5 (3.4) | -3.93 (<0.001) | 0.12 | 1.42 | 6.3% ^c | 9.6% | -0.55 (0.580) |
| Illness identity: rejection | 2.1 (0.9) | 2.2 (0.9) | -2.72 (0.007) | 0.09 | 0.43 | 8.3% ^c | 11.7% | -0.91 (0.364) |
| Illness identity: acceptance | 4.1 (0.9) | 4.1 (0.9) | 0.41 (0.684) | -0.01 | 0.38 | 12.4% | 11.2% ^b | 1.34 (0.182) |
| Illness identity: engulfment | 1.8 (0.8) | 1.9 (0.9) | -1.32 (0.188) | 0.03 | 0.32 | 9.6% ^c | 10.2% | -1.14 (0.256) |
| Illness identity: enrichment | 2.9 (1.1) | 3.0 (1.1) | -3.30 (0.001) | 0.08 | 0.41 | 11.0% | 15.8% ^b | -0.60 (0.548) |
| Empowerment | 59.1 (8.4) | 59.2 (8.4) | -0.44 (0.658) | 0.02 | 3.56 | 11.9% | 12.6% ^b | -0.66 (0.510) |
| Social support: significant other | 6.0 (1.3) | 6.0 (1.3) | -1.00 (0.317) | 0.02 | 0.55 | 7.7% | 8.0% ^b | -1.20 (0.229) |
| Social support: family | 6.0 (1.2) | 5.9 (1.3) | 2.79 (0.005) | -0.06 | 0.52 | 9.6% | 5.8% ^b | -0.81 (0.418) |
| Social support: friends | 5.7 (1.2) | 5.7 (1.3) | 1.11 (0.268) | -0.03 | 0.53 | 10.0% | 8.8% ^b | 0.29 (0.775) |
| Social support: total | 5.9 (1.0) | 5.9 (1.0) | 1.05 (0.296) | -0.006 | 0.37 | 10.6% | 9.4% ^b | -0.78 (0.436) |
| Support from parents | 5.9 (1.2) | 5.9 (1.3) | 1.65 (0.100) | -0.01 | 0.42 | 9.1% | 8.3% ^b | -1.20 (0.229) |
| Concerns about future health | 4.7 (2.6) | 4.7 (2.6) | -0.89 (0.376) | 0.03 | 1.12 | 6.5% ^c | 7.4% | 0.14 (0.890) |
| PREM | | | | | | | | |
| Support by healthcare providers | 5.5 (1.1) | 5.5 (1.1) | -2.37 (0.018) | 0.07 | 0.53 | 8.7% | 11.4% ^b | -1.70 (0.089) |

MCID, minimal clinically important difference.

[§]Paired t-test.

[¶]Independent sample t-test.

^aProportion of patients that have an increase or decrease higher than the MCID between pre- and peri-pandemic measurements.

^bAn increase in score reflect an improved status of the patient.

^cA decrease in score reflect an improved status of the patient.

ical activity level was only slightly lower during the first pandemic wave (March–May 2020), but had increased by the second wave (October–December 2020).³⁶ The impact of lockdowns also had a small effect on mental health, as shown in a meta-analysis of 25 longitudinal studies conducted in the general population.³⁷ Nonetheless, children, adolescents, and parents of children under 5 years of age experienced greater impact of the pandemic on their psychological well-being than other groups.^{38,39} In response to the anticipated mental health consequences, the Lancet’s COVID-19 Commission Mental Health Task Force was established. This Task Force reviewed the literature and confirmed a significant rise in psychological distress during the early months of the pandemic.³⁹ However, the most recent data suggest that most, but not all, metrics of psychological distress returned to baseline by mid-2020.³⁹ This may explain the findings of the current study that peri-pandemic scores on the PROMs and PREM did not substantially differ from pre-pandemic scores. This highlights the immense value of longitudinal data when evaluating the impact of major stressors.

The present findings may be somewhat reassuring for CHD clinicians. Although patients from Belgium, Norway, and South Korea

commonly reported that the pandemic had negatively impacted their social lives, mental health, and professional lives/education, and had also contributed to increased worry and fear, differences in PROMs and PREM scores from pre- to peri-pandemic were negligible. This is in line with observations from the general population.⁴⁰ Indeed, a large majority of the general population adapted very well to the COVID-19 crisis and psychological distress dropped towards pre-pandemic levels.⁴⁰ Individual responses, of course, depended on the resilience of individuals. In this respect, it is known that people with CHD have a relatively strong resilience, one that is stronger than for instance that of blood cancer survivors.⁴¹ Also a strong sense of coherence, which is an expression of resilience, has been observed in people with CHD.^{42,43} This pre-existing resilience, which has been found to be a predictor of emotional functioning over time,⁴⁴ may have been a psychologically protective factor during the pandemic. Perhaps adults with CHD have a history of managing health-related anxiety and stressors⁴⁵ that was advantageous in this situation. In line with the movement of positive psychology, this suggests that clinicians should not only look at limitations and impediments, but that resources and capacities also deserve attention.

Although PROM and PREM outcomes of the study sample as whole were cautiously reassuring, results must not be interpreted to suggest that significantly psychosocial distress or quality of life impairment during the pandemic have been rare. At the individual patient level, some will have been affected more drastically during this particular period than others, particularly if they lost loved ones to COVID or had significant changes in employment or living circumstances. In the clinical setting, the only way to know how an individual patient is coping with the pandemic is to ask them. Adequate mental healthcare for vulnerable individuals is thus indispensable,³⁹ especially because we do not know yet what the long-term consequences of the pandemic will be.

The present findings are clearly reassuring for researchers who are currently investigating PROMs and PREMs in CHD. Studies that are conducted in the peri-pandemic period, but outside the acuity of the first lockdown, are unlikely to result in significantly biased findings. This is important for the large-scale international APPROACH-IS II project that is currently in progress in over 60 centres around the world. The data that are currently collected may largely represent the standard situation of patient-reported outcomes and experiences of adults with CHD.

Methodological considerations

The present study has several strengths. (i) It comprises a relatively large sample of adults with CHD from three countries, with different pandemic trajectories. Belgium has been heavily hit in terms of positive cases and mortality, whereas in South Korea, the pandemic was relatively under control in the timeframe of this study. This disparity in the course of the pandemic across the countries increases the generalizability of the present findings. Nonetheless, the severity of the pandemic did not moderate the evolution of PROMs and PREM over time in this study. (ii) Data on PROMs and PREM were collected immediately prior to the first wave of the COVID-19 pandemic, thus providing a unique opportunity to longitudinally assess the potential impact of the pandemic. (iii) Well-established questionnaires with strong psychometric properties, and available in different languages, were employed.

However, there were also some methodological limitations that have to be considered when interpreting the findings. (i) Eighteen percent of patients who participated in the pre-pandemic assessment could not be re-enrolled for the peri-pandemic assessment. A potential bias as a result of this cannot be completely excluded. (ii) We did not have a control group of healthy people. Hence, we could not directly compare the scores and evolution over time with healthy counterparts. Nonetheless, our findings are confirming previous observations in the general population,^{39,40} which supports the validity of our results. (iii) Although we could appraise the general pandemic situation in the three countries, we could not adjust for the actual situation in the region where patient lives. For instance, the infection and mortality rates could be very low because the local lockdown measures were very stringent. Therefore, the present study would not allow us to evaluate the impact of specific preventive measures on PROMs and PREM. (iv) We included one peri-pandemic assessment and we do not know the future course of the pandemic. Consequently, we cannot make long-term projections for

the impact of the COVID-19 pandemic on the well-being of adults with CHD.

Conclusions

This longitudinal, international study showed that the mid-term impact (6–12 months after the start) of the COVID-19 pandemic on PROMs and PREM of adults with CHD was limited. The effect sizes were negligibly small and in 73–86% of the patients, the PROMs and PREM remained within MCID boundaries. A history of COVID-19 infection did not moderate the evolution of PROMS and PREM. These findings are cautiously reassuring for clinicians and researchers in CHD. Yet, the long-term consequences of the pandemic must still be investigated.

Supplementary material

Supplementary material is available at *European Journal of Cardiovascular Nursing* online.

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Data availability

The data underlying this article can be shared on reasonable request to the corresponding author.

Registration

ClinicalTrials.gov: NCT04902768.

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