BMJ Open Health-related quality of life in postcardiac interventional catheterization patients with congenital heart disease: a mixed-methods study protocol from Pakistan

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To cite: Ali F, Ladak LA, Usmani AA, *et al.* Health-related quality of life in postcardiac interventional catheterization patients with congenital heart disease: a mixed-methods study protocol from Pakistan. *BMJ Open* 2021;**11**:e052989. doi:10.1136/bmjopen-2021-052989

► Prepublication history for this paper is available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2021-052989>).

FA and LAL are joint first authors.

Received 01 May 2021
Accepted 04 November 2021

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ABSTRACT

Introduction Improvement in health-related quality of life (HRQoL) has been reported in patients with congenital heart disease treated with interventional cardiac catheterization; however, there is a significant dearth of literature from low/middle-income countries (LMICs) about this aspect. Multiple factors like sociodemographic and cultural differences, variable procedural outcomes due to lack of technical expertise and limited resources and inconsistent postprocedure follow-up may affect HRQoL in LMICs. This protocol paper aims to describe the study methodology to determine the HRQoL and its predictors in patients who have undergone interventional cardiac catheterization. Conclusions from this protocol study will help prepare a holistic approach to delivering care to patients in low-resource settings.

Methods and analysis A mixed-methods study design will be used. The quantitative arm will compare the HRQoL of these postcardiac interventional catheterization patients with their age-matched healthy siblings to identify the HRQoL predictors, whereas the qualitative arm will further explore the experiences of these patients and parents. A minimum number of 108 patients of age 2 years and above, at least 6 months postinterventional catheterization follow-up and ability to understand Urdu/English will be enrolled. PedsQL 4.0 Generic Core Scales, PedsQL Cognitive Functioning Scale and PedsQL 3.0 Cardiac Module will be used. The Student's t-test will analyse the difference in the means of HRQoL between patients and siblings. Multiple regression will identify HRQoL predictors. A subsample of enrolled patients and parents will be interviewed and analysed using directed content analysis (a qualitative component of the study).

Ethics and dissemination Ethics approval has been obtained from Ethics Review Committee of The Aga Khan University, Pakistan (ERC #2020-3456-11808). Study findings will be published in peer-reviewed journals and presented at conferences.

INTRODUCTION

Congenital heart disease (CHD) demonstrates a critical global health issue^{1–4} with significant morbidity and mortality. Current

Strengths and limitations of this study

- A prospective, mixed-methods study from Pakistan (representative of a low-resource setting) exploring the contextual factors contributing to health-related quality of life (HRQoL) in children with congenital heart disease postcardiac interventional catheterization.
- Identifying predictors of HRQoL will facilitate developing interventional strategies to modify these factors and may help improve the HRQoL in such patients.
- The study methodology only gives a snapshot view of the HRQoL and thus does not inform us about improving or worsening HRQoL related to the procedure.
- PedsQL questionnaires have been used in low/middle-income countries, and have been reported to have a high reliability, but are still in the validation process; hence cross-cultural bias is possible.
- Since it is a single-centre study, findings will be limited to similar resource-limited settings and types of procedures performed on the cohort of the recruited patients.

estimates of prevalence rates range between 10 and 12/1000 live birth, with most children residing in low/middle income countries (LMICs).^{5 6} Advancement in congenital cardiac surgery has significantly improved the outcomes of patients with CHD. Similar advances have been made in the treatment of many CHD conditions in the cardiac catheterization laboratory. Interventional cardiac catheterization has become the treatment of choice for some common CHDs without subsequent cardiac surgery, and hence most paediatric cardiac catheterization laboratories have transformed into therapeutic suits.^{7–9} Besides yielding comparable outcomes to surgery, these procedures offer

other benefits, such as decreased lengths of stay, lower rates of infection and lesser complications, culminating in better cost-effectiveness. It holds true not only in treatment of certain shunt lesions¹⁰ and balloon valvuloplasty of valves;^{11–13} but also in complex cases, such as transcatheter perforation of atretic pulmonary valves and endovascular stenting for coarctation of aorta (CoA).^{14 15}

As the routine clinical assessment does not entirely reflect disease symptoms, functional limitations or social and mental effects of the treatment, therefore it is critical to consider the role of health-related quality of life (HRQoL) for a holistic assessment of the patient. HRQoL is a multidimensional concept that includes physical, mental, emotional and social functioning domains. It goes beyond direct measures of population health, life expectancy and causes of death; and focuses on impact of health status on quality of life. Therefore, several questionnaires have been designed to assess HRQoL^{16–20} quantitatively, and it has been strongly suggested that HRQoL be assessed using both generic and disease-specific questionnaires. However, studies focusing on assessing HRQoL postcardiac catheterization, especially in LMICs, are scarce.^{21 22} In some studies, sociodemographic factors like high SES,²³ education of parents²⁴ and living with family²³ are associated with good HRQoL. To understand the relationship of biological function, symptoms, functional status and general health perception along with the individual and environmental characteristics of the available resources on HRQoL, the theoretical model of Wilson and Cleary model of HRQoL, modified by Ferrans *et al* (figure 1) is helpful.²⁵

Our primary aim is to explore the HRQoL in children with CHD postcardiac catheterization by comparing them with their age-matched healthy siblings as a control group. Our secondary aim is to determine the effects of different patients' and procedure-related factors on their postprocedure HRQoL. Additionally, we seek to assess the effect of a novel procedure efficacy variable (a composite measure of technical success and adverse events) which will categorise the procedure efficacy as ideal, adequate and inadequate; for five common interventional cardiac catheterization procedures²⁶ on HRQoL. Furthermore, we will also inquire about the study population's perceptions and experiences (through the qualitative interview)

Figure 1 Revised Wilson and Cleary model for health-related quality of life.

to gather their comprehensive perspective about HRQoL. Using a mixed-methods design will provide an in-depth and comprehensive understanding of HRQoL in our study population.

Due to socioeconomic and cultural differences, we anticipate that there may be specific differences in postprocedure HRQoL in the patients with CHD from LMICs compared with their counterparts in high-income countries (HICs). In our study, we expect that a large proportion of our patient population will be from a low socioeconomic class, and thus, findings from our study may be generalisable to large subset of such patients living in low-resource settings. Such a study will help us identify gaps in care delivery and thus inform interventions to address issues with HRQoL.

METHODS

Aim

This protocol paper describes the methodology to explore HRQoL in CHD patients, postcardiac interventional catheterization.

Research questions

Following questions will be addressed.

1. What is the HRQoL of patients with CHD postcardiac catheterization as compared with their age-matched sibling?
2. What are the predictors (sociodemographic, clinical and procedure-related) of HRQoL in patients with CHD?
3. What are patient's experiences with CHD and their parents related to catheterization, recovery from the procedure and living with CHD?

Study setting

The study will be conducted at The Aga Khan University Hospital (AKUH) in Karachi, Pakistan, a tertiary care hospital, where cardiac interventional catheterization services for patients with CHD have been available for the last two decades. Approximately 200–250 children with CHD from diverse backgrounds and ethnicities undergo congenital cardiac catheterization (diagnostics and interventional) per year at AKUH.

Study design

It is a prospective mixed-methods study using a convergence model of concurrent triangulation, which will supplement each other in understanding the HRQoL in this patient population. Data will be gathered through structured interviews using quantitative and qualitative approaches. Both interviews will be conducted simultaneously during the same session (non-sequential method). This approach not only provides convenience to the participants but also better engagement during the interviews. In addition, our patient population will participate from across the country; hence, this approach also

provides practical feasibility by decreasing the cost of frequent transportation.²⁷

Eligibility

All patients (≥ 2 years) with common CHD who are at least 6 months post-cardiac interventional catheterization and able to understand Urdu/English will be included. Patients who underwent congenital cardiac catheterization but in whom intervention was deferred or failed due to inadequate anatomy subsequently requiring surgical correction; those with a chromosomal abnormality, non-cardiac significant disabilities like neurological and renal failure and diagnostic congenital cardiac catheterization will be excluded.

Quantitative arm

It will be used to compare the HRQoL of patients with their controls and identify its predictors.

Recruitment of participant

Patients with CHD, their parents and age-matched siblings as controls within ± 2 years of the age difference of the patient with CHD will be recruited. Age-matched siblings are chosen as a control in a country like Pakistan to account for confounders like genetics, sociodemographic and sociocultural factors, racial and ethnic diversity present within the same locality and the practicality of recruitment given the limited funds to conduct the study. Given that the average sibling size in a household in Pakistan is ~ 5 individuals, we are confident of recruiting siblings as controls.^{28 29} Matching based on gender will be preferred wherever possible to account for gender-based differences in HRQoL, which may still be a limitation that will be difficult to control. The cases and control overmatching in results may influence external validity;³⁰ hence, a paired, matched analysis and conditional logistic regression will mitigate it.

Selection of procedure

All congenital cardiac interventional catheterization procedures will be included. The case types and severity categories³¹ will be included in the list of predictors for HRQoL.

Sample size

The sample size is calculated based on eight predictors of HRQoL in CHD patient population as identified in the literature,^{22 32} including income, parental education, family structure, gender, procedural risk category, age at procedure, procedure outcome and cardiac medication. To see the effect size that suggests clinically meaningful changes, we kept a small Cohen's *d* effect size of 0.15 between CHD and their age-matched sibling, using a power of 80% and a probability of 0.05, a minimum sample size of 108 per group (case and control) is calculated. Though the magnitude of a change in HRQoL is small, it may be experienced as important by the patient. 'A 4.4 change in the PedsQL 4.0 (total scale score for child self-report), while a 4.5 change in PedsQL 4.0

(total scale score for parent proxy-report) was determined as a minimal clinically meaningful difference'.³³ As also argued by Middel and van Sonderen,³⁴ it is vital to consider both the statistical and clinically meaningful differences as even when the magnitude of a change in HRQoL is small, it may be experienced as significant by the patient.

Data collection methods, training and tools

Due to the COVID-19 pandemic and consequent situation, some modifications have been made for data collection. All eligible study populations will be approached via phone call for enrollment; those who do not want to come to AKUH but are interested in participating in the study will be interviewed via telephonic call or WhatsApp audio/video or Zoom link (as preferred by the study participant) after taking telephonic-verbal informed consent/assent. Those who want to visit AKUH to participate in the study will be interviewed using the same structured questionnaire, as the one used virtually, by the data collector after obtaining the written consent/assent form. Standards for personal protective equipment will be followed according to institutional-directed guidelines for both parents, children with CHD, their siblings and the data collector. Either one or both parents will be allowed to participate in the interview. In addition, the same parent will be recruited for both quantitative and qualitative interviews to control for parental perception bias. There may be chances of gender-based perceptions already highlighted in the literature,³⁵ which is one of our study's limitations. The consolidated criteria for reporting qualitative research checklist will be used to ensure transparency in reporting the findings of the study. The patients will be recruited from the year 2000 to 2020. The anticipated time for recruitment is approximately 8–10 months.

Training and tools

Research assistance (RA) and medical students will be trained via a two-phase session for quantitative interviews. In the first session, these questionnaires will be taught by a subject specialist Laila Akbar Ladak (LAL) and paediatric cardiologist Fatima Ali (FA), and in the second session, hands-on practice will be done on simulated patients. In addition, initial 10% of all interviews will be recorded after informed consent, and will be cross checked by LAL and FA.

Information will be collected on sociodemographic, clinical and procedural data, and PedsQL questionnaires 4.0 will be used for structured interviews. Permission to use these questionnaires has been attained from the Mapi Research Trust, and translation has been done in compliance with the WHO's guidelines in English and Urdu (the local language spoken in Pakistan). These tools have well-established validity, tested in HICs.^{33 36} High reliability has been reported from a study from LMICs,³² the validity of these tools is still in process, and hence there is a possibility of cross-cultural bias.

Demographic data

Sociodemographic data will be collected from patients with CHD, parents and siblings to characterise the participant's current age, gender, socioeconomic background, educational status, occupation and family structure. In addition, patients will be asked for their current cardiac medication details (if any) and New York Heart Association functional class to assess their physical functional status. Though there is no 'gold standard' for measuring socioeconomic status (SES), based on the literature, the indicators of SES will be used, including the family income, structure education and residential place (urban vs rural).³⁷ The authenticity of family income will be cross-checked indirectly during quantitative and qualitative interviews by exploring nature of occupation, employment status, welfare assistance needed to seek care and area of residence. Many of these variables can give the investigator a fair idea of the authenticity of income earned.

Clinical and procedural data

Patient's clinical and procedural data will be retrieved from their medical records. It will include the type of CHD (shunt or obstructive lesion), age at diagnosis and procedure, name of the procedure, type of catheterization procedure (device closure, valvuloplasty stent or valve placement or creation of shunts), re-intervention and case type risk category.³¹

A novel procedural efficacy variable (a composite of technical success and adverse events) will also be used to determine the effect of the procedure on HRQoL. Procedural efficacy will be classified as ideal, adequate and inadequate (table 1) as previously described,²⁶ this variable is available for common procedures including pulmonary and aortic valvuloplasty, atrial septal defect and patent ductus arteriosus device closure, and CoA stenting. For complex and uncommon procedures like ventricular septal defect device closure, we will collect the data on complications and adverse events (not as a composite measure) and will be factoring it on a case-to-case basis.

PedsQL questionnaire

We will use both generic and disease-specific questionnaires in this study. Generic Core Module (V.4.0) will be used, which have 23 items for overall HRQoL, Cognitive functioning scales has 6 items for cognitive assessment and Cardiac module (V.3.0), which is for disease-specific HRQoL assessment, has 27 items (table 2). These questionnaires are available for populations of different ages, which includes young children aged (5–7 years), children (8–12 years), teenagers (13–18 years), young adults (18–25 years) and adults (>26 years) as well as for toddlers (2–4 years) parents/proxy version, due to developmental limitations on self-report in <5 years, which has very similar response items and scoring.³⁸ These questionnaires capture patient experiences for the last month. Since this is a cross-sectional study, depending on how far

out from their procedure a patient is interviewed, long-term effects of the procedure (complications, re-interventions and residual lesions) will be captured in some and will be missed in others. Since the data are being collected only once from patients with CHD, after their interventional catheterization procedure, pre-catheterization/postcatheterization comparison of HRQoL to determine changes related to the procedure may not be possible.

The questionnaires have the same response items and scoring. Both, patients with CHD and their parents will be asked to rate HRQoL from 0 to 4 with 0 being 'never a problem' and four being 'almost always a problem'. Responses will be reverse-scored and linearly transformed to 0–100, with a higher score indicating better HRQoL. If more than 50% of the items in the scale are missing, the scale scores will be considered as missing data. The Psychosocial Health Summary Score will be calculated by adding the sum of the items over the number of items answered in the Emotional, Social and School Functioning Scales. A mean score of the individual domains will be calculated by adding the sum of the items over the number of items answered. The total score will be the sum of all the items over the number of items answered on all scales.

Statistical analysis for quantitative data

Data will be analysed using the IBM SPSS Statistics V.22. Means and SD and median and IQR will be calculated for continuous variables, and frequencies will be calculated for categorical variables. We will ensure for data completeness. However, in case of any missing data, participant's data in that particular domain will not be included in the overall analysis. This will further be highlighted in the manuscript write up in the participant's recruitment and data analysis section. Two-sided paired t-tests with a p value of <0.05 as statistically significant will be used to calculate the differences in HRQoL between the cases and their age-matched sibling's controls. The effect size will be calculated using Cohen's d to identify the magnitude of HRQoL difference on PedsQL questionnaires. A Cohen's d of 0.2 will be considered small, 0.5 as a medium and 0.8 as a large effect size.³⁹ Generalised linear models (GLMs) will be used to explore the relationship between general and cardiac-specific HRQoL scores and socio-demographic/clinical and procedure-related variables. Differences in mean scores between patients with postintervention catheterization and siblings will be calculated for each domain of HRQoL and will be included as a dependent variable in the model. A separate model will be created for cardiac-specific HRQoL domains. Independent variables identified in the literature will be selected to be included in models for both general as well as cardiac-related HRQoL. These variables will include age at diagnosis, name, number, type and risk category of procedure, current cardiac medications, gender, parental education, socioeconomic background and family structure. Linearity, homoscedasticity (validating homogeneity of variance using scatter plots of residuals and predictors,

Table 1 List of criteria for procedural efficacy by procedure

Ideal	Adequate	Inadequate
PDA device closure		
▶ No residual shunt	▶ Mild residual shunt around device	▶ ≥Moderate residual shunt around device
▶ No aortic gradient (echo)	▶ Aortic gradient >2 m/s but not requiring intervention	▶ Impingement of PA or aorta leading to device removal
▶ No LPA gradient (echo)	▶ LPA gradient >2 m/s but not requiring intervention	▶ LPA gradient >2 m/s but requiring intervention
▶ No device-related hemolysis	▶ Device-related hemolysis not requiring intervention	▶ Device-related hemolysis requiring a cath or surgical intervention or Device-related hemolysis leading to renal dysfunction
▶ Elective home discharge	▶ Elective home discharge	▶ Delayed home discharge
▶ AES level 1	▶ AES level 2–3	▶ AES level 4–5
ASD device closure		
▶ No residual flow (echo)	▶ Residual flow <3 mm	▶ Residual flow ≥3 mm
▶ No AV valve impingement	▶ AV valve impingement without regurgitation	▶ AV valve impingement with regurgitation
▶ No intracardiac thrombus	▶ No intracardiac thrombus	▶ Intracardiac thrombus
▶ No pericardial effusion	▶ Trace pericardial effusion	▶ ≥Mild pericardial effusion
▶ Elective home discharge	▶ Elective home discharge	▶ Delayed home discharge
▶ AES level 1	▶ AES level 2–3	▶ AES level 4–5
Coarctation of aorta stenting		
▶ Gradient <20 mm Hg (cath)	▶ Residual gradient 20–30 mm Hg	▶ Residual gradient >30 mm Hg
▶ No aneurysm	▶ No aneurysm	▶ Aneurysm formation
▶ No tear	▶ Tear not requiring intervention	▶ Tear requiring intervention
▶ Normal pulse	▶ Normal pulse	▶ Radio femoral delay
▶ No stent migration or jailing of vessels	▶ Stent migration resolved in same procedure	▶ Stent migration requiring reintervention
▶ No Head/neck vessels jailing	▶ Head/neck vessels jailing requiring reintervention.	▶ Head/neck vessel jailing requiring reintervention
▶ Elective home discharge	▶ Elective home discharge	▶ Delayed home discharge
▶ AES level 1	▶ AES level 2–3	▶ AES level 4–5
Aortic valvuloplasty		
▶ Valve PSEG <35 mm Hg (cath)	▶ Valve PSEG 35–50 mm Hg	▶ PSEG ≥50 mm Hg
▶ No new AR	▶ New mild AR	▶ New moderate–severe AR
▶ Normal pulse	▶ Normal pulse	▶ Abnormal pulse character
▶ AES level 1	▶ AES level 2–3	▶ AES level 4–5
Pulmonary valvuloplasty		
▶ Valve PSEG <30 mm Hg	▶ Valve PSEG 30–50 mm Hg	▶ Valve PSEG ≥50 mm Hg
▶ Trace/mild PR (echo)	▶ Moderate PR	▶ Severe PR
▶ No new TR	▶ New mild TR	▶ New moderate/severe TR
▶ No MPA/RVOT tear	▶ MPA/RVOT tear not requiring intervention	▶ MPA/RVOT tear requiring intervention
▶ Elective home discharge	▶ Elective home discharge	▶ Delayed home discharge
▶ AES level 1	▶ AES level 2–3	▶ AES level 4–5

Findings in the above criteria are based on the latest assessment during that admission. AES levels are based on previously published criteria.³¹

Ideal=When all criteria meet, Inadequate=presence of any criteria described above.²⁶

AES, adverse event severity; AR, aortic regurgitation; ASD, atrial septal defect; AV, atrioventricular; LPA, left pulmonary artery; MPA, main pulmonary artery; PA, pulmonary artery; PDA, patent ductus arteriosus; PR, pulmonary regurgitation; PSEG, peak systolic ejection gradient; RVOT, right ventricular outflow tract; TR, tricuspid regurgitation.

Table 2 Quantitative assessment tool description**A: Quantitative assessment**

Scales (total item)	Domain	items
Generic Core Scale ²³	Physical	8
	Emotional	5
	Social	5
	School	5
Cognitive Functioning Scale ⁶	Cognitive	6
Cardiac Module ²⁷	Heart problem	7
	Treatment	5
	Perceived physical appearance	3
	Treatment anxiety	4
	Cognitive problem	5
	Communication	3

assuming that all the data points are close to the regression line), multicollinearity and residuals' normality will be checked to ensure the data met the GLM required assumptions. If the graphs tend to form a funnel shape at the higher end of the predicted values, it will be an indicator of heteroscedasticity (unequal variance across the different levels of the independent variables). In that scenario, weighted GLM analysis will be performed based on the assumption that by adding the weights (least square of the variance), homoscedasticity variance of the predicting variables will be achieved across the regression line. A weighted GLM analysis will be conducted to address the heteroscedasticity for total HRQoL; all GLMs will be found to be plausible for all the domains.⁴⁰

Qualitative approach

A qualitative approach will be used to gather the perception and experience of the HRQoL of postcardiac

interventional catheterization patients with CHD and their parents.

Participants and sample size

Sample size and stratified purposive sampling by age group will guide the recruitment of the participants. These subsamples will be recruited from the ~108 participants of the quantitative interviews. A minimum of 5–7 patients from each age group (13–18 years, 19–25 years, 25+ years) and parents of patients from each age group (1–4 years, 5–12 years) will be invited to participate in the qualitative arm of the study.⁴⁰ Final numbers will be guided by process of data saturation where major themes are richly described, and no new themes are developing. We would maintain the credibility of the qualitative data by participation equity for patients by gender, age and type of catheterization procedure.

Data collection

Qualitative data will be collected using individual interviews based on a semistructured interview guide (table 3) by a subject specialist (LAL) and Paediatric Cardiologist (FA).

This guide has been designed based on the literature from HICs⁴¹ and LMICs²² and in discussion with experts in this field, that is, two paediatric cardiologists (FA, BH), an HRQoL subject specialist (LAL). Topics addressed during the interview include the children with CHD/parent's perception of HRQoL related to CHD catheterization, identification of the domains of HRQoL that are most important to them during recovery, the areas where the impact of the CHD catheterization has been most and least beneficial, the problems/challenges faced and their perceived needs for the future.

Data analysis plan

Interview data will be analysed using directed content analysis guided by the Wilson-Cleary theoretical model of HRQoL (figure 1). In directed content analysis, the

Table 3 Questions for qualitative assessment**B: Qualitative assessment**

	For patients	For parents
1	In your view, what is the quality of life?	In your view, what is quality of life for your child?
2	How do you see your disease that is, congenital heart disease and catheterization?	How do you see your child's disease, that is, congenital heart disease and catheterization?
3	How do the community and society view your congenital heart disease and catheterization?	How does the community and society view your child's congenital heart disease and catheterization?
4	What is the most disturbing or bothersome aspect of your catheterization?	What is the most disturbing or bothersome aspect of your child's catheterization procedure?
5	How do you deal with these issues and problems?	How do you/your child deal with these issues and problems?
6	What are some of the concerns that are very important for you to discuss for your future years?	What are some of the very important concerns for you to discuss for your child's future years?
7	What do you think are the needs of patients with congenital heart disease with catheterization, and what would you like to suggest to the healthcare professionals to address those needs?	What do you think are the needs of patients with congenital heart disease with catheterization, and what would you like to suggest to the healthcare professionals to address those needs?

Table 4 Moon's plea for more conceptual and methodological rigour' 10 question's checklist⁴²

S. #	Questions	Our response
1	Did the investigators give a definition of quality of life?	Yes
2	Did the investigators state the domains, they will measure as components of quality of life?	Yes
3	Did the investigators give reasons for choosing the instruments they used?	Yes
4	Did the investigators aggregate results from multiple items, domains or instruments into a single composite score for quality of life?	Yes
5	Were patients asked to give their own global rating for quality of life?	Yes
6	Was overall quality of life distinguished from health-related quality of life?	Yes
7	Were patients invited to supplement the items listed in the instruments offered by the investigators that they considered relevant for their quality of life?	Yes
8	If so, were these supplemental items incorporated into the final rating?	Yes
9	Were patients allowed to indicate which items were personally important to them?	Yes
10	If so, were the importance ratings incorporated into the final rating?	Yes

initial coding is guided by an existing theory or research findings. As researchers, the transcripts will be read and re-read to identify the common themes, subthemes and categories grouped under elements of the theoretical framework and are interpreted against the researcher's understandings of the social, cultural, clinical and demographic profile of the participants. Two members of the research team will review the transcripts and will have an agreement on the analysis to enhance the credibility of the findings. Moreover, all measures will be done to ensure the qualitative data rigour.⁴¹ It is essential in conducting HRQoL studies that methodological limitations must be recognized and addressed. We used 10 questions as a checklist and guidance for the future framework from Moon's plea for more conceptual and methodological rigour^{42 43} (table 4).

Quality control

RA will be trained by an HRQoL specialist (LAL) about the study processes, including recruitment, data collection/management and data storage. A pilot will also be done to ensure that the study processes are followed in compliance with the study proposal. Interviews will be conducted in a dedicated quiet room in the study setting, if participants will be willing to visit the hospital or via either telephone, Zoom or WhatsApp, depending on participant choice. For the quality check of the interviews, initial 10% of quantitative and qualitative interviews will be recorded and checked by the principal investigator (FA, LAL) within 24–48 hours; 2–3 interviews

will be conducted initially and later, the frequency will be increased to 5–6 per day for five working days. All the interviews will be conducted in English or Urdu based on the participant's preferences. All qualitative interviews will be recorded and conducted by LAL and FA.

Those patients who will be identified for the need of medical checkups will be referred to their respective cardiologists and, if needed, will get financial support from a previously established endowment fund dedicated to the care of patients with CHD.

Ethical concerns and dissemination

Data confidentiality would be strictly maintained. The patient's anonymity would be maintained by giving a unique identifier. All the hard copy data would be kept in lock and key, and soft copy would be password protected with access to investigators only. Data would be stored for 5 years as per good clinical practice guidelines and institution policy. Study findings would be disseminated through publications and presentations at a relevant conference without highlighting patient identification maintaining patient confidentiality.

Patient and public involvement

Previous work from our group has demonstrated significantly lower HRQoL in LMIC CHD patients' postsurgery compared with their counterparts in HICs.²² In addition, individual and sociocultural factors were also highlighted by the participants, which influenced their HRQoL. We inferred the findings of these studies in our CHD patient population, who underwent interventional cardiology in our context and setting. However, we did not directly involve the study population, parents and the public in developing the research methodology.

Second, COVID-19 pandemic limited our direct involvement with the patients and parents in person. We will recruit the study population and parents via a telephonic approach where the study purposes, study-required processes and the time commitment will be explained following their consent to participate in the study. The study will be conducted through structured validated questionnaires. Interviews will be conducted via telephonic call or in-person visits to the study site as per their feasibility. We intend to disseminate the main results to study participants and seek study population, parents and public involvement in developing an appropriate method of dissemination.

Contributors FA, LAL and BH have contributed equally to the study concept, designing and developing the protocol, methodology and statistical writing. AAU, HAR and MTS have contributed to study design and protocol writing.

Funding This study was funded by The Aga Khan University, University Research Seed Money grant (Seed money grant PF 142/1019).

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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