PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Impact of a nurse-led teleconsultation strategy for cardiovascular disease management during COVID-19 pandemic in India: A pyramid model feasibility study
AUTHORS	Mohan, Bishav; Singh, Bhupinder; Singh, Kavita; Naik, Nitish; Roy, Ambuj; Goyal, Abhishek; SIngh, Gurbhej; Aggarwal, Shivaansh; Saini, Aftabh; Tandon, Rohit; Chhabra, Shibba; Aslam, Naved; Wander, Gurpreet; Prabhakaran, Dorairaj

VERSION 1 – REVIEW

REVIEWER	Bhaskar, Sonu South Western Sydney Local Health District, Liverpool Hospital, Department of Neurology & Neurophysiology
REVIEW RETURNED	11-Nov-2021

GENERAL COMMENTS	This is an interesting study on nurse-led teleconsultation cardiovascular disease management during COVID-19 from a resource-limited setting. The protocol is overall well written, however, there are some concerns regarding study design, patient selections and other questions/comments which I invite authors to clarify and expand upon. 1. One major concern about this study is: authors state that this was meant for CVD management during COVID-19, however, in design settings authors specify that the CVD patients with OPD visits during Sept 2019-March 2020 were offered this consultation mode. Can the authors clarify when actually were the patients contacted (period)? Were all consecutive patients considered? What was the rationale for choosing this time period? In Table 2, the authors report 64 patients, (8.4%) were included who were referred for admission? Referred for admission for what? For CVD related procedures or investigation? This needs clarification. Moreover, it is not clear what was the criterion that was applied to be considered CVD patients? Presenting with CVD symptoms or previous diagnosis? Please clarify. Who reviewed the patient files and made the decision to contact patients from the stated period prior to making a contact? Was it reviewed by the nursing staff or OPD physicians or done independently by the study investigators? 2. Authors state that "The patients with mechanical prosthetic valve or those receiving oral anticoagulation therapy were excluded from the study as these patients were followed up using a different treatment protocol and participated in a separate research study. " Why were these patients excluded from this study? This is a major concern from methodological design. Do these patients qualify under the CVD criterion? It is not clear why they were excluded - the rationale that they were considered for a separate study is not

	sufficient. This indicates the presence of selection bias as well as concerns for subgroup analysis out of the main study. Was the study protocol presented here the same as the one for which ethics approval was obtained? If available, could you provide the publication on the other study? This will allow an open appraisal of the study design for any overlap with the current study. 3. Please avoid repeating the same information as given in the Tables in Results. Page 8 (2-4 paragraphs) starts with a Table. Rather, please indicate key findings and how it's relevant to this study or contextual to the current study. 4. In the Discussion, it is relevant to add some context to the findings - by citing other relevant literature on telemedicine from elsewhere in India or overseas (see https://pubmed.ncbi.nlm.nih.gov/32613010/, https://pubmed.ncbi.nlm.nih.gov/33669951/) 5. In the results, suggest to include a statement that nursing-led consultation, as demonstrated in this study, was well tolerated and easy to implement. 6. Page 10: Lines 28-31: Authors state, "Virtual consultations could certainly be explored for its clinical use in urban and rural areas to further improve the efficacy and impact of teleconsultations as care delivery model" Please provide a suitable reference (e.g., suggest https://pubmed.ncbi.nlm.nih.gov/33014958/ https://pubmed.ncbi.nlm.nih.gov/34442159/)

REVIEWER	Cartledge, Susie Monash University, School of Public Health and Preventive Medicine
REVIEW RETURNED	25-Jan-2022

GENERAL COMMENTS	Thank you for the opportunity to review this paper which exaimines the feasibility of impelmenting a nurse-led teleconsultation strategy for cardiovascular patients in India. I think this is a timely and interesting paper that will be of interest to the readership. I hope my comments and questions below will strengthen the paper. Title - I would suggest amending the title to incldue a more methodological description - while pyramid model study is described, I'm not sure many people would be familiar with that and I think the fact the study is a descriptive, feasability study is more important for the title Abstract - reads well and is clear - however in the conlusion - mentions that the program was low cost, however the paper does not mention cost or provide any costing details/cost analysis. Introduction - clear and well written Methods - IPD not fully described until the results - please spell out at the first occassion the abbreviation is used - Question - why were all patients (n = 12042) included for teleconsultation? A rationale is never provided. My questions would be - do they all need a teleconsultation, is this a good use of

	resources to include them all and not triage them a bit further? Can you provide more inforamtion/justification? - while the satisfaction survey was pre-tested, was it developed from any validated tools available? If not, was there not a validated tool that met the study's needs? Results - can you elaborate on the access to medicines? Was this due to not being able to leave home due to COVID or was it due to supply at the phamacy or other issues? - it is not typical to start each paragraph of the results by leading the the table number and then describing the table. Can you start each paragraph with the leading result from that section instead and reference the associated table within the text? Discussion - can you provide a comment on whether the clinicians felt constrained by audio only? - I was suprised to read that a 24-hour call mobile phone number was provided to patients (as this is an impressive service to offer!) - can you comment on how much this was used and what for? Was it needed? - Other questions I was hoping would be covered in the discussion - what are the future steps? Will this be implemented into practice long-term - can you provide any comment on cost or is a future cost analysis planned? - can you provide a comment on how the health system in India works and whether the clinicans/systems were reimbursed for these consultations? - limiations well covered but may also include some of the above points that I have raised Conclusion - I wonder about the statement of providing teleconsultations for routine care post COVID... I don't think they can replace all routine care as physical assessment is critical for cardiac patients and also includes things like taking ECGs etc. I would consider tempering this statement.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Dr. Sonu Bhaskar, South Western Sydney Local Health District, Ingham Institute Comments to the Author:

This is an interesting study on nurse-led teleconsultation cardiovascular disease management during COVID-19 from a resource-limited setting. The protocol is overall well written, however, there are some concerns regarding study design, patient selections and other questions/comments which I invite authors to clarify and expand upon.

Response: Thank you for your encouraging comments. We have responded below to your very thoughtful, helpful comments/queries.

1. One major concern about this study is: authors state that this was meant for CVD management during COVID-19, however, in design settings authors specify that the CVD patients with OPD visits during Sept 2019-March 2020 were offered this consultation mode.
Can the authors clarify when actually were the patients contacted (period)?
Response: Thank you for your insightful comment. From the hospital electronic database containing records of patients who previously attended either the out-patient CVD clinic or in-patient hospitalization between Sept 2019 – March 2022, were considered as the sampling frame (target patients with proven history of CVD) as these patients were expected for their next clinic visit in 4-6 months and could have suffered due to the travel restrictions imposed due to the COVID-19 related lockdowns. During the COVID-19 related lockdowns imposed in India between 25 March – May 2020, we contacted the selected patients with CVD from hospital database for teleconsultations. (Refer page no. 5)

Were all consecutive patients considered?
Response: Yes, all patients who previously attended the outpatient or inpatient department at the Cardiology unit of Dayanand Medical College (DMC) Ludhiana Hospital were contacted and provided care using the nurse-led telemedicine approach. (Refer page no. 5)

What was the rationale for choosing this time period?
Response: Thank you for your query. We selected last 6 months: Sep 2019 – Mar 2022 to retrieve patient's data from the hospital database/electronic records of patients who attended the clinic in the previous 6 months period because these patients either had an emergency visit to DMC hospital for CVD or were receiving regular CVD care from DMC hospital consultants. Stable CVD cases are normally expected for the next clinic visit in 4-6 months, and those who were recently hospitalized required to meet physician within a month. Therefore, it was prudent and practical approach to first select and target the CVD patients who attended DMC Hospital in the last 6 months period. (Refer page no. 5)

In Table 2, the authors report 64 patients, (8.4%) were included who were referred for admission? Referred for admission for what? For CVD related procedures or investigation? This needs clarification.
Response: Thank you for your comment. During the implementation of nurse-led teleconsultations, we found 64 patients (8.4%) required a referral for hospital admission. These admissions were required for diagnostic evaluation and management of acute coronary syndrome or worsening heart failure symptoms. (Refer page no. 9)

Moreover, it is not clear what was the criterion that was applied to be considered CVD patients? Presenting with CVD symptoms or previous diagnosis? Please clarify.

Response: Thank you for asking this question. The criteria applied to be considered CVD patients, included all patients who had a previous diagnosis of CVD and were followed up earlier in Cardiology OPD or had an in-patient hospitalization, with proven cardiovascular disease such as coronary heart disease, heart failure, hypertension, peripheral vascular diseases, cardiomyopathies, arrhythmic disorders. All patients with valid contact numbers received teleconsultations. (Refer page no. 5)

Who reviewed the patient files and made the decision to contact patients from the stated period prior to making a contact? Was it reviewed by the nursing staff or OPD physicians or done independently by the study investigators?
Response: The patients' records were retrieved and reviewed by the trained nursing staff from the DMC hospital medical records and electronic database. As stated above all the patients with proven history of cardiovascular diseases were first contacted by nurses for the telephone follow-up. (Refer page no. 6)

2. Authors state that "The patients with mechanical prosthetic valve or those receiving oral anticoagulation therapy were excluded from the study as these patients were followed up using a different treatment protocol and participated in a separate research study. "
Why were these patients excluded from this study? This is a major concern from methodological design. Do these patients qualify under the CVD criterion? It is not clear why they were excluded - the rationale that they were considered for a separate study is not sufficient. This indicates the presence of selection bias as well as concerns for subgroup analysis out of the main study. Was the study protocol presented here the same as the one for which ethics approval was obtained? If available, could you provide the publication on the other study? This will allow an open appraisal of the study design for any overlap with the current study.

Response: Thank you for this insightful comment. The patients with mechanical prosthetic valve or those receiving oral anticoagulation therapy were not included in this study as these patients required mandatory hospital visits for investigations or for managing their anticoagulation. Even during the stringent lockdown such patients were seen in the hospital. They therefore did not fit into this protocol. Instead, the patients on oral anticoagulation therapy were included in a separate research study and results from this study is now published (See reference: Singh G, Kapoor S, Bansal V, Grewal M, Singh B, Goyal A, Tandon R, Chhabra ST, Aslam N, Wander GS, Mohan B. Active surveillance with telemedicine in patients on anticoagulants during the national lockdown (COVID-19 phase) and comparison with pre-COVID-19 phase. Egypt Heart J. 2020 Oct 16;72(1):70. doi: 10.1186/s43044-020-00105-w. PMID: 33064222; PMCID: PMC7562770.) (Refer page no. 5)

3. Please avoid repeating the same information as given in the Tables in Results. Page 8 (2-4 paragraphs) starts with a Table. Rather, please indicate key findings and how it's relevant to this study or contextual to the current study.

Response: Thank you very much for your comment. We have re-organized the results section and now reporting only the key findings and its contextual relevance to the current study. (Refer page no. 8 - 9)

4. In the Discussion, it is relevant to add some context to the findings - by citing other relevant literature on telemedicine from elsewhere in India or overseas (see https://pubmed.ncbi.nlm.nih.gov/32613010/, https://pubmed.ncbi.nlm.nih.gov/33669951/)
Response: Thank you for your comment.
We have cited both the suggested references in the discussion section. (Refer page no. 11)

5. In the results, suggest to include a statement that nursing-led consultation, as demonstrated in this study, was well tolerated and easy to implement.
Response: Thank you for this helpful suggestion. We added this statement in the results section. (Refer page no. 9)

6. Page 10: Lines 28-31: Authors state, "Virtual consultations could certainly be explored for its clinical use in urban and rural areas to further improve the efficacy and impact of teleconsultations as care delivery model" Please provide a suitable reference (e.g., suggest https://pubmed.ncbi.nlm.nih.gov/33014958/ https://pubmed.ncbi.nlm.nih.gov/34442159/)
Response: Thank you for your comment.
We have added these references in the discussion section. (Refer page no. 11)

Reviewer: 2
Dr. Susie Cartledge, Monash University
Comments to the Author:
Thank you for the opportunity to review this paper which examines the feasibility of implementing a nurse-led teleconsultation strategy for cardiovascular patients in India. I think this is a timely and interesting paper that will be of interest to the readership. I hope my comments and questions below will strengthen the paper.
Response: Thank you for your very thoughtful, helpful comment.

Title

- I would suggest amending the title to include a more methodological description - while pyramid model study is described, I'm not sure many people would be familiar with that and I think the fact the study is a descriptive, feasibility study is more important for the title

Response: Thank you for this suggestion. Sure, we have added the term “feasibility study” in the title. (Refer page no. 1)

Abstract

- reads well and is clear
- however, in the conclusion - mentions that the program was low cost, however the paper does not mention cost or provide any costing details/cost analysis.

Response: Thank you for flagging this. We have edited the conclusion section and removed the mention of “low cost”. (Refer page no. 2)

Introduction

- clear and well written

Response: Thank you.

Methods

- IPD not fully described until the results - please spell out at the first occasion the abbreviation is used

Response: Thank you for noting this. We have expanded the term IPD=in-patient department in the methods section. (Refer page no. 5)

- Question - why were all patients (n = 12042) included for teleconsultation? A rationale is never provided. My questions would be - do they all need a teleconsultation, is this a good use of resources to include them all and not triage them a bit further? Can you provide more information/justification?

Response: Thank you for clarifying. The patients included in this study were already diagnosed cases of cardiovascular diseases (and previously attended the DMC Hospital in-patient or out-patient clinic over the last 6 months: September 2019 – March 2020). The guidelines recommend that patients with proven CVD to follow up regularly in the outpatient clinic every 3-6 months depending up on the severity of illness. Therefore, 12042 patients with proven CVD who attended the Dayanand Medical College (DMC) hospital in the past 6 months constituted the sampling frame for this feasibility study. Also, the DMC Hospital sees around 6000-7000 patients every month. Therefore, 12042 patients with

CVD was the number awaiting/needing a clinic follow up which was conducted over the telephone using the telemedicine-based treatment protocol. (Refer page no. 5)

- while the satisfaction survey was pre-tested, was it developed from any validated tools available? If not, was there not a validated tool that met the study's needs?
Response: Thank you for clarifying this. The treatment satisfaction survey was adapted from a validated tool previously used in several other studies called as “Diabetes Treatment Satisfaction Questionnaire”. We have provided a citation for the tool now. (Refer page no. 7)

Results
- can you elaborate on the access to medicines? Was this due to not being able to leave home due to COVID or was it due to supply at the pharmacy or other issues?
Response: Thank you for this query. To clarify, the difficulty in “access to medicine” was due to multiple factors such as non-availability of the local pharmacies in the villages (most of the study participants were from villages), non-availability of some specific brand name medicines in the nearby pharmacies, or absence of a caregiver or helping hands in the family. (Refer page no. 8)

- it is not typical to start each paragraph of the results by leading the table number and then describing the table. Can you start each paragraph with the leading result from that section instead and reference the associated table within the text?
Response: Thank you very much for your comment. We have revised the results section as per your suggestions. (Refer page no. 8, 9)

Discussion
- can you provide a comment on whether the clinicians felt constrained by audio only?
Response: Thank you for your insightful comment. The physicians expressed some hesitancy in providing teleconsultation on audio-only mode. This has been highlighted as the limitation in the respective section. However, in this study we did not collect qualitative interview data on the experiences of providers delivering care using the telemedicine strategy. (Refer page no. 11)

- I was surprised to read that a 24-hour call mobile phone number was provided to patients (as this is an impressive service to offer!) - can you comment on how much this was used and what for? Was it needed?
Response: Thank you. To clarify, the 24-hour call facility is provided as a part of routine care in the Dayanand Medical College (DMC) hospital in the emergency department. For this study, the mobile

phone facility was placed in the emergency department of DMC Hospital, Ludhiana. The usual problems which were encountered during the night call included high blood pressure recordings, excessive sweating, not getting adequate sleep, uneasiness, etc.

- Other questions I was hoping would be covered in the discussion
  - what are the future steps? Will this be implemented into practice long-term

Response: Given that COVID-19 pandemic is now receding in most parts of India, as a next step we propose a hybrid model of care and a larger study involving multiple hospitals utilizing a hub and spoke model of care, which can be first expanded to one state, i.e., Punjab, and the results from this larger multi-center study can inform further scale-up to other states in India.

  - can you provide any comment on cost or is a future cost analysis planned?

Response: Thank you for this astute comment. Cost is an important consideration to inform the overall value of this nurse-led telemedicine strategy and to further inform the state- or national-level scale-up of this pyramid model-based telemedicine strategy. Unfortunately, we did not collect costs or resource utilization details during this study to be able to perform a cost analysis. However, a future larger study across multiple centers, will also collect cost measures, cost of delivering the care and then, we can conduct budget impact analysis and project the cost of national-level scale-up. (Refer page no. 12)

  - can you provide a comment on how the health system in India works and whether the clinicians/systems were reimbursed for these consultations?

Response: Thank you for your comment. The healthcare delivery system in India is fragmented and heterogenous with a mix of private and public health facilities, government health centers pay a standard monthly salary to the health care professionals, and private hospitals follow different mode of payment or reimbursement models either based on total number of consultations or duty hours. (Refer page no. 12)

- limitations well covered but may also include some of the above points that I have raised

Response: Thank you for your comment. Yes, we have added the relevant limitations to this study. (Refer page no. 12)

Conclusion

- I wonder about the statement of providing teleconsultations for routine care post COVID... I don't think they can replace all routine care as physical assessment is critical for cardiac patients and also includes things like taking ECGs etc. I would consider tempering this statement.
Response: Thank you for your comment. As per your suggestion, we have revised the conclusion section to recommend now a hybrid model of care post COVID to minimize resource utilization and cost of care but also focusing on physical assessment for critical cardiac care. (Refer page no. 12)

VERSION 2 – REVIEW

REVIEWER	Bhaskar, Sonu South Western Sydney Local Health District, Liverpool Hospital, Department of Neurology & Neurophysiology
REVIEW RETURNED	30-Mar-2022

GENERAL COMMENTS	No further comments.

REVIEWER	Cartledge, Susie Monash University, School of Public Health and Preventive Medicine
REVIEW RETURNED	14-Apr-2022

GENERAL COMMENTS	Well done to the authors for addressing all reviewers comments in a satisfactory way. My only remaining comments are: Paragraph 1 of the results is quite long - I would suggest breaking into two around line 21.