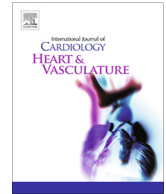




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'Routine' versus 'Smart Phone Application Based – Intense' follow up of patients with acute coronary syndrome undergoing percutaneous coronary intervention: Impact on clinical outcomes and patient satisfaction

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ABSTRACT

Background: Acute coronary syndrome (ACS) refers to the spectrum of clinical presentation of coronary artery disease (CAD). As a routine practice at our institute, following PCI, ACS patients are called for the first follow up after two weeks. This period of two weeks can be full of anxieties, concerns and medical issues. In this study, we planned to assess the feasibility/acceptability of smart phone application (app) based system for patient follow-up and its comparison to routine practice among patients with ACS who have undergone a PCI.

Methods: A randomized controlled trial (RCT) was conducted over a period of one year from January to December 2017. After the PCI was deemed successful, patients were recruited and enrolled based on the understanding of basic English language and operation of a smart phone. Those who consented to be part of study were then randomly allocated either the conventional follow up group or the intense follow up (routine + smart phone app based follow up) group. First co- primary outcome was composite of clinical outcomes (mortality, myocardial infarction, stroke, target vessel revascularisation, heart failure admission and emergency visit). Second co- primary outcome was patient satisfaction. The overall patient satisfaction was assessed by the patients using a five-point patient satisfaction survey instrument containing five questions with 5 marks each, in which higher scores meant more satisfaction. Secondary outcome was controlled hypertension in hypertensive patients. It was defined as systolic BP less than 130 and diastolic BP less than 80 mmHg.

Results: A cohort of 228 patients (109 in intense app-based arm; 119 in routine follow up arm) were analyzed. The result showed significant improvement in blood pressure control in hypertensive population in intense app based follow up group (76.2%) when compared to routine follow up group (45%) with p value 0.0062. The satisfaction score was significantly higher in the intense app based follow up (20.7 ± 1.29) as compared to routine follow up (16.5 ± 2.68); p value 0.0001. In the intense app based follow up 72.5% patient felt it was excellent tool (score 21–25) while 27.5% categorized it as good (score 16–20). While the routine follows up was perceived as good by most (91.6%) of the patients. Only 4.2% graded it as excellent and an equal number (4.2%) graded it as a poor way of follow up.

Conclusions: App based system shows higher satisfaction rate and comparable clinical outcome when compared to traditional hospital based follow up protocol alone. It has a high acceptance rate and thus this system should be explored further to optimize long term patient care.

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Patient Satisfaction Questionnaire:

1. I am fully satisfied with the medical care I have been receiving.
Strongly Agree (5) Agree (4) Uncertain (3) Disagree (2) Strongly Disagree (1)
2. I think my doctor's Hospital has everything needed to provide complete care.
Strongly Agree (5) Agree (4) Uncertain (3) Disagree (2) Strongly Disagree (1)
3. My doctor and their team treat me in very friendly and courteous manner.
Strongly Agree (5) Agree (4) Uncertain (3) Disagree (2) Strongly Disagree (1)
4. My doctors are careful to check everything when treating and examining me.
Strongly Agree (5) Agree (4) Uncertain (3) Disagree (2) Strongly Disagree (1)
5. I am satisfied with the follow-up care after discharge.
Strongly Agree (5) Agree (4) Uncertain (3) Disagree (2) Strongly Disagree (1)

Fig. 1. Patient Satisfaction Questionnaire.

1. Introduction

Acute coronary syndrome (ACS) refers to the spectrum of clinical presentation of coronary artery disease (CAD) that includes unstable angina (UA), ST segment elevation myocardial infarction (STEMI) and non ST segment elevation myocardial (NSTEMI) [1]. Reported as the 'deadliest disease' globally, CAD is a major health concern, with a huge economic burden. In India, CAD is a major contributor to mortality not only among the aged population but also among the young adults, and unfortunately, the trend is on rise in India. In 2001–2003 CAD accounted for 17% of total deaths and 26% adult deaths, which increased to 23% of total and 32% of adult deaths in 2010–2013 [2].

Percutaneous Coronary Intervention (PCI), whenever available is the treatment of choice for ACS [3]. Despite the good outcome following a timely PCI, the rates of long-term morbidity in terms of recurrence are substantial. In India as well as in other developing nations the need for implementation of secondary prevention strategies is huge [4]. Following PCI, titration of Guideline directed medical therapy (GDMT) as recommended by the American college of cardiology (ACC), European society of cardiology (ESC), for secondary prevention like aspirin, statin, and anti-hypertensive agents in a tailored way is the most crucial step to prevent long-term sequel and recurrences.

As a routine practice at our institute, following PCI, ACS patients are called for the first follow up after two weeks, wherein their cardiac status is assessed and drugs are titrated. For obvious reasons this two weeks period for the patient who has experienced an ACS, and has undergone an invasive procedure for the same, can be full of anxieties, concerns and medical issues.

We hypothesized that a smart phone application (app) based system, wherein the patient is able to communicate with his/her health care providers, in addition to the routine follow up protocols might have a positive impact in clinical outcome and patient satisfaction among patients with ACS who have undergone a PCI.

2. Material & methods

This randomized controlled trial (RCT) took place at a University Hospital of North India, over a span of one year (January – December 2017). The institutional ethical committee approved the study protocol. The sample size was calculated on the basis of patient enrolment data of year 2016. A total of 1980 patient underwent

PCI for an ACS. As sample was to be collected from a consultant's OPD. So, of six days OPD one nit was estimated to have approx. 330 per year. Keeping a drop of 30% in enrolment with a type I error rate (alpha) of 5% and a type II error rate (beta) of 20%, sample size of 231 was calculated. After the PCI was deemed successful, patients were recruited and enrolled based on the understanding of basic English language and operation of a smart phone. Written informed consent was obtained after 24–48 h following the procedure, once the patient was clinically stable and fit for discharge. Those who consented to be part of study were then randomly allocated either the conventional follow up group or the intense follow up (routine + smart phone app based follow up) group. Simple randomization was done with computer generated numbers.

All participants were called to the hospital for the routine protocol of follow up after two and subsequently four weeks following the index procedure. However, in the intense app based follow up arm patients received additional benefit of direct communication with their health care providers as and when required during this duration. To facilitate this communication at the time of discharge for this group of participants the app (HealthRADAR by Evolko) was installed in the smart phone of the patient and all medical information and health related data was fed in the app by one of the investigators. With the help of this app the patients were able to clarify their doubts and discuss their minor problems directly with their health care providers by means of a message. The provider could then at his/her ease and time see the query and instruct changes in management plan online. For symptoms and events which were either equivocal in nature or deemed serious necessitating direct supervision of a physician, patient was advised to contact nearby health facility or report back to the hospital. We hypothesized that this system not only decreases anxiety of the patient but also reduces unnecessary patient visits to the hospital and saves doctor's precious time during the outpatient hours.

HealthRADAR by Evolko Systems Inc. California, USA - HealthRADAR is a smart phone based solution which allows doctors to review self-monitoring updates of the long-term care patients and interact with them via chat. The Artificial Intelligence (AI) algorithms of HealthRADAR prompts the patient to interactively enter BP, Pulse, pertinent symptoms etc. on their smart phones. The system asks further questions based on the response of the patient. HealthRADAR analyzes the data and sends the clinical summary to the specialist. The doctor reviews the details for an early warning, chat with the patient, and alters the treatment (if needed) before the next regular visit. It saves precious time of

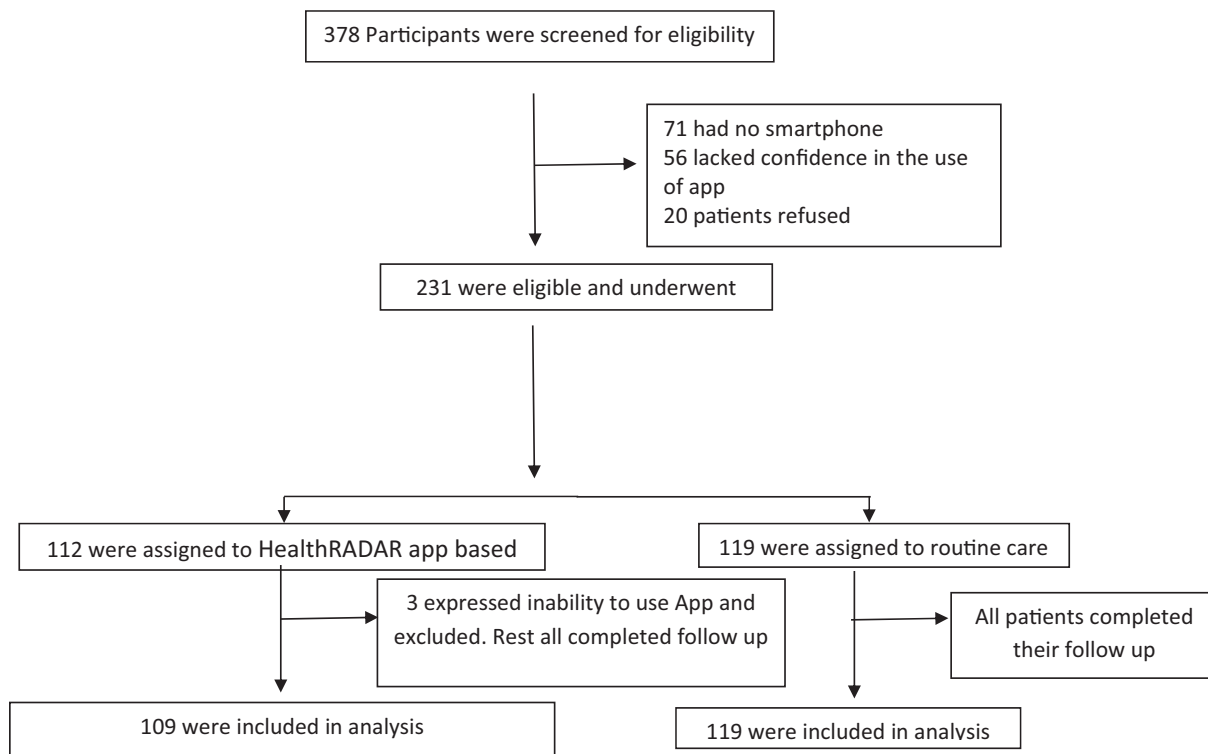


Fig. 2. Flow chart of sample enrolment in the study.

Table 1
Comparison of Baseline Characteristics in Routine vs. Intense app. Based Follow up of Post Intervention ACS Patients.

Characteristics		Intense (n = 109)	Routine (n = 119)	P-value
Age (years)	Mean ± SD	54.3 ± 11.3	54.2 ± 10.2	0.973 ^{NS}
Age group (years), n (%)	20 – 29	3 (2.8)	1 (0.8)	0.780 ^{NS}
	30 – 39	6 (5.5)	5 (4.2)	
	40 – 49	27 (24.8)	31 (26.1)	
	50 – 59	31 (28.4)	37 (31.1)	
	60 – 69	36 (33.0)	35 (29.4)	
	70 – 79	6 (5.5)	10 (8.4)	
Sex, n (%)	Male	88 (80.7)	102 (85.7)	0.313 ^{NS}
	Female	21 (19.3)	17 (14.3)	
Diagnosis, n (%)	STEMI	57 (52.8)	65 (54.6)	0.784 ^{NS}
	NSTEMI	40 (37.0)	45 (37.8)	
	USA	11 (10.2)	9 (7.6)	
Risk factors, n(%)	Diabetes	36 (33.0)	30 (25.2)	0.194 ^{NS}
	Hypertension	42 (38.5)	40 (33.6)	0.364 ^{NS}
	Smoking	54 (49.5)	64 (53.8)	0.522 ^{NS}
Ejection Fraction (%)	Mean ± SD	51.2 ± 7.5	46.4 ± 4.6	0.001 ^{***}
Treatment at Discharge	Aspirin	107(98.1)	116(97.5)	0.724 ^{NS}
	Clopidogrel/Prasugrel/ Ticagrelor	104(95.4)	114(95.8)	0.887 ^{NS}
	Statin	108(99.1)	116(97.5)	0.359 ^{NS}
	Beta blockers	64(58.71)	71(59.66)	0.359 ^{NS}
	ACE I/ARB	56(51.3)	64(53.78)	0.716 ^{NS}

the specialists while the patient saves money and gets timely expert advice. The detailed representation of the app is given in Fig. 4.

Statistical Analysis: After the completion of study descriptive statistics were used to summarize demographic and clinical variables of the target population. Data collected via the application were utilized to show trends and frequency distributions of questions related to patient’s recovery at the end of two consecutive hospital follow up 4 weeks apart, first being 2 weeks after the procedure. First co- primary outcome was composite of clinical outcomes (mortality, myocardial infarction, stroke, target vessel revascularisation, heart failure admission and emergency visit). Second co- primary outcome was patient satisfaction. Secondary

outcome was controlled hypertension in hypertensive patients. Statistical analysis was done using GraphPad Prism 6. P value ≤ 0.05 was considered to be statistically significant. Patient satisfaction in both groups was scored and compared based on a small five-point patient satisfaction survey instrument (Fig. 1).

3. Results

A total of 378 patients underwent PCI for ACS over a period of 1 year (Jan 2017 to Dec 2017) at the recruiting unit. Of total 305 were male and 73 were females. Mean age of the study population (n = 228) was 54.24+/-10.7, male 190 (83.3%) female 38 (16.7%).

Table 2
Comparison of Short Term Clinical Outcomes at Thirty days in Routine vs. Intense app Based Follow up of Post Intervention ACS Patients.

Outcome	Intense (n = 109)	Routine (n = 119)	P-value
1. Primary outcome:			
A. Composite of clinical outcomes (mortality, myocardial infarction, stroke, target vessel revascularization, heart failure admission and emergency visit)	14 (12.8)	18 (15)	0.620 ^{NS}
B. Patient Satisfaction Score	16.569	13.269	less than 0.001 ^{***}
2. Secondary outcome:			
Controlled blood pressure/Total Hypertensive, n (%)	32/42 (76.2)	18/40 (45.0)	0.0062 ^{***}

231 patients with a diagnosis of ACS were randomized in the study. The details of sample enrolment is given in Fig. 2. Out of them 112 were randomly assigned the intense smart phone app based follow up arm (that included routine hospital based follow up plus smart phone app based communication with the health care provider), while 119 were selected for the routine hospital based follow up arm. Three patients from the intense follow up arm demonstrated their inability to use the app effectively and thus were removed from the study. Therefore, the cohort for final analysis included 228 patients (109 in intense app based arm; 119 in routine follow up arm). Completion rate of the smart phone app in the study was 97.3% Fig. 2.

The demographics or better clinical characteristics of patients belonging to the two arms were tabulated and were found to be statistically comparable except for the ejection fraction (Table 1). Mean ejection fraction in the intense app based follow up arm at the time of presentation (51.2 ± 7.5%), was significantly higher as compared to the routine follow up arm (46.4 ± 4.6%) (Table 1).

On comparing the short-term clinical outcome (first co primary outcome); a composite of clinical outcomes (mortality, myocardial infarction, stroke, target vessel revascularization, heart failure admission and emergency visit) at 30 days - follow up was found to be statistically non significant. Incidence of composite outcome was 12.8% (14 out of 109 patients) in routine follow up ; 15% (18 out of 119 patients) in intense app based follow up; p value 0.620. The only significant difference in the two groups was found in the proportion of patients with controlled blood pressure (intense app based follow up 76.2% (32 out of 42 hypertensive); routine follow up 45% (18 out of 40 hypertensive); p value 0.0062) (Table 2). The mean time of patient contact to consultant through app was through 1.2 times per patients while three patient were referred to visit hospital for urgent evaluation.

The overall patient satisfaction (second co primary outcome) as subjectively reported by the patients in a five point scoring system in which higher scores meant more satisfaction, was significantly higher in the intense app based follow up (20.7 ± 1.29) as compared to routine follow up (16.5 ± 2.68); p value 0.0001. In the intense app based follow up 72.5% patient felt it was excellent tool (score 21–25) while 27.5% categorized it as good (score 16–20). Conversely the routine follow-up was perceived as fairly good by most (91.6%) of the patients. Only 4.2% graded it as excellent and an equal number (4.2%) graded it as a poor way of follow up (Fig. 3).

4. Discussion

This study demonstrates the high completion rate (97.3%) and satisfaction rate (72.5% - excellent) of an intense smart phone app based follow up system combined with the routine follow up protocol among patients who underwent PCI for ACS.

Owing to the improvement of medical technology and better understanding of natural history and disease progression, mortality from ACS has declined substantially [5]. Yet the estimates are

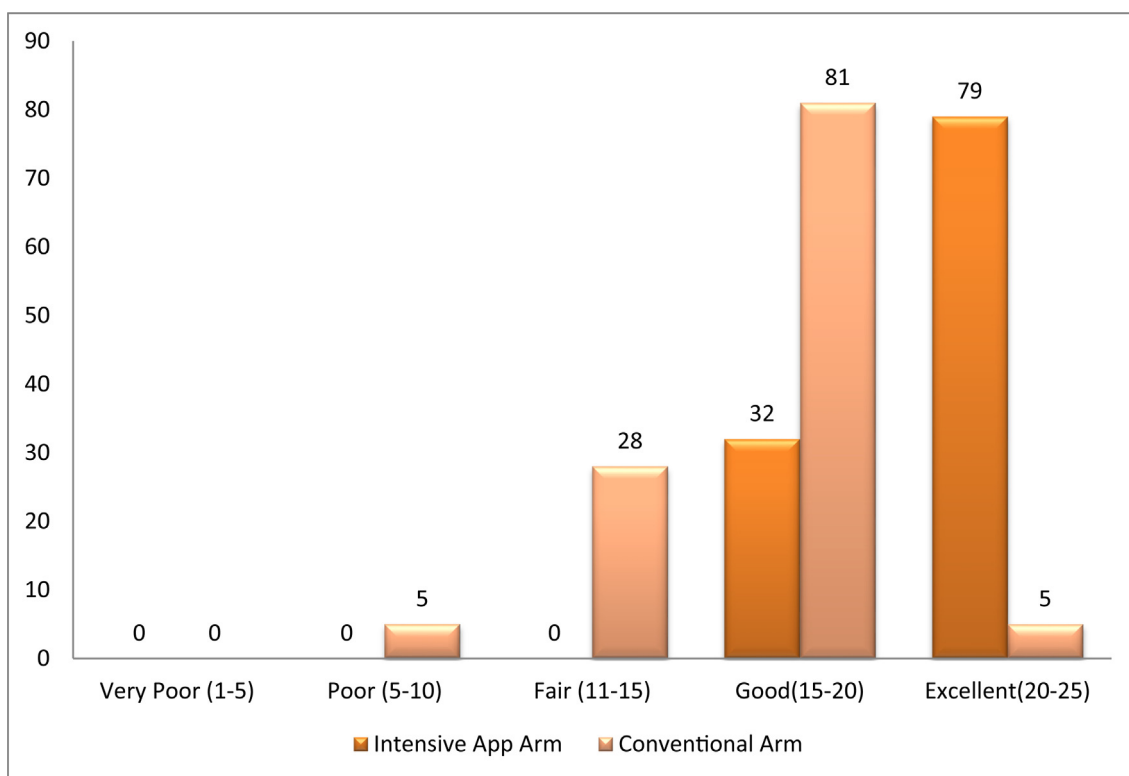


Fig. 3. Patient Satisfaction Score among Intense Follow-up and Routine Follow-up.

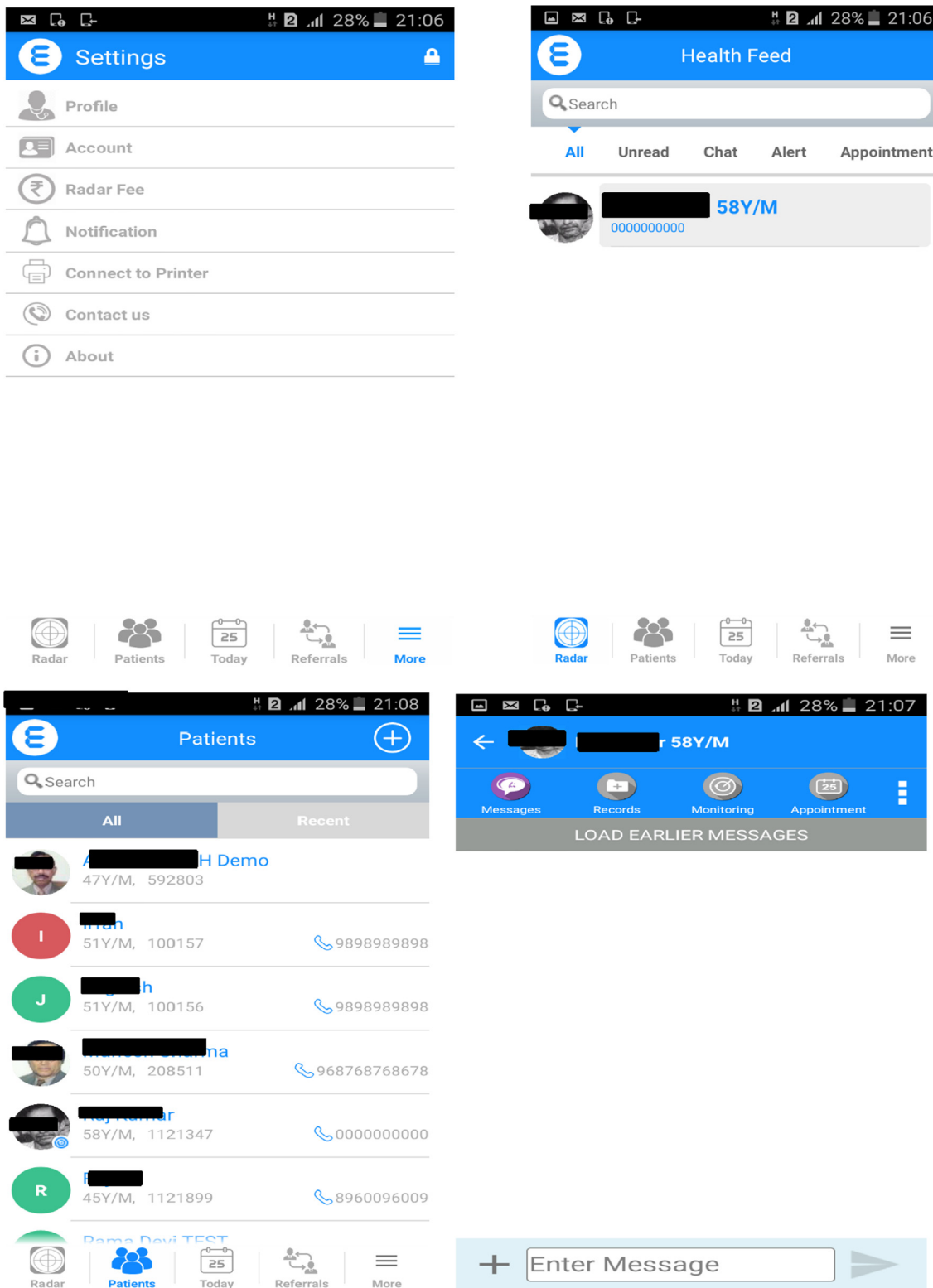


Fig. 4. Preview of smartphone application to be used in the study.

that 40% of the patients who experience ACS will die within 5 years with the risk of death being 5 to 6 times higher in individuals who experience a recurrent event [6–8]. Thus, ACS being an entity with a significant mortality rate require a close follow up. Even when the acute event has been taken care of with the best possible therapies, follow up of patients for secondary prevention and early diagnosis of recurrence or related events is of the utmost impor-

tance. Encouragingly in RCTs following an ACS event, with structured treatment regimens and frequent follow-up protocols, the compliance rate is high and recurrent event rate is low [9].

Despite improvements in management and survival after primary ACS hospitalization, early readmissions remain common, posing significant clinical and financial impact. Though readmissions within 30 days after discharge for an ACS are common, it is

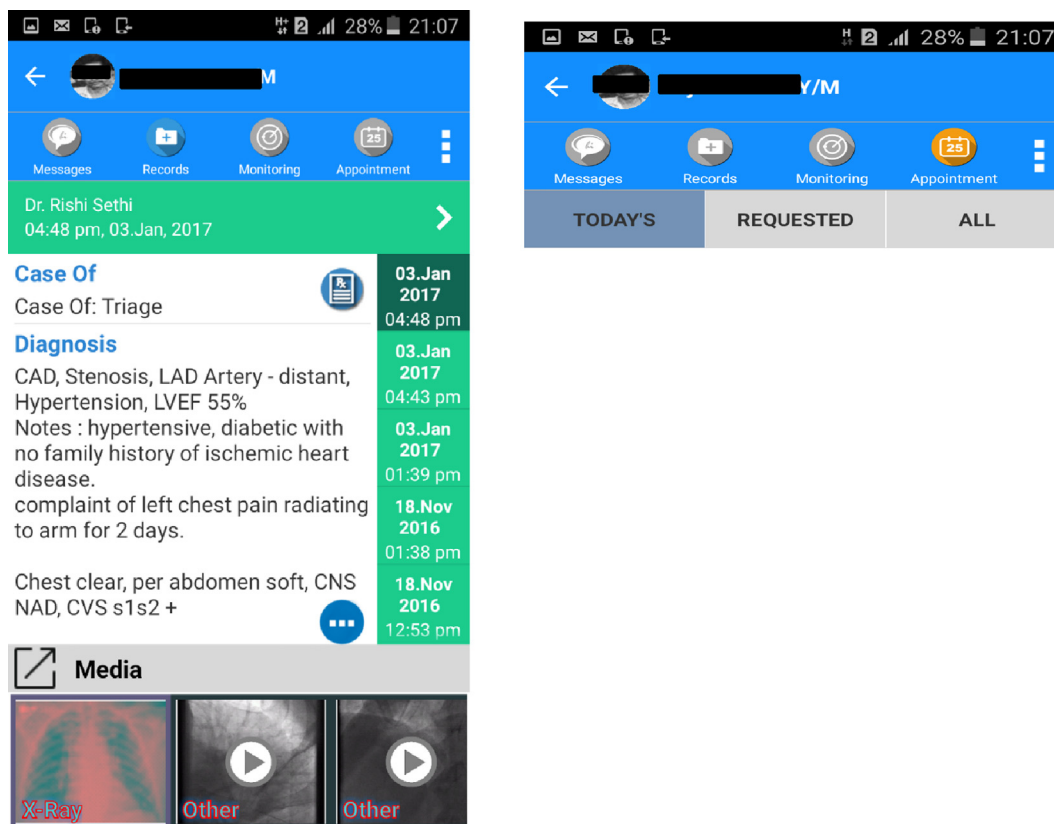


Fig. 4 (continued)

realized that these readmissions are rather heterogeneous in nature and that many readmissions are unrelated to the index ACS event and complication associated with it [10].

We are living in an era of rapid technological revolution and medical field is also trying to explore its potential in various arenas; may it be creating health awareness among the masses, triaging patients in the hospital or providing home based follow up. The adult population of twenty first century is an extremely important group which is tech-comfortable. Owing to the sound understanding and growing friendliness of the present population to the technological advancements, smart phone based apps in medical field can be a boon for this generation for regular use as well as for designing and development of apps for future generations [11,12].

As far as cardiovascular health is concerned, there are apps available to target preventive strategies for cardiovascular diseases (CVD), to access cardiac rehabilitation and to facilitate behavioral changes [13–15]. To the best of our knowledge, the present study is the first RCT to utilize an app-based technology in following up patients with ACS who have undergone PCI procedure.

Smart phone App based follow up of patients has a theoretical potential to reduce the direct and indirect (loss of work related) cost of hospital visits for the patients [16,17]. On other hand, this system will also avoid unnecessary cluttering of outpatient departments for trivial reason, thus optimizing health care providers' time. This pilot study is an effort to analyze the short-term clinical outcome of patients treated for ACS with or without a smart phone app, while both arms undergoing routine protocol based hospital follow up. We also tried to compare the overall rate of satisfaction between the two groups.

Previously a RCT of around 700 patients of coronary heart disease in Australia has shown the benefit of mobile phone text messaging service compared with usual care by showing improvement in LDL-C level in blood pressure, BMI, and smoking status [18].

Meta analysis involving 16 RCTs found that mobile telephone text messaging increased adherence to taking medications among middle-aged patients with chronic disease. Although most trials were of short duration and used self reported outcome measures [19].

Not many studies in literature have attempted to evaluate the efficacy of health-related smartphone apps. There is even less information about consumers' behavior and use of such apps. Although our study was performed in a small cohort in a short time span it definitely shows the high acceptance as well as satisfaction rate of target population where the anxieties and demands to connect with the health care providers are higher.

The HealthRADAR system that we used in this study provided insightful trends on daily indicators of post intervention ACS recovery, such as chest pain, dyspnea, blood pressure control, feelings of anxiety, and the limitations of the physical activity. This gave physician important recovery information not often discussed during routine follow-up visits and at time points to which they would not otherwise have access. The utilization of this method provided the health care provider with an easy, portable way to monitor subjective quality of recovery on a real-time basis. Continued collection of aggregate data on this patient population will provide the care team with a method of identifying patients who fall outside the normal variances of postoperative recovery. This will also allow physician to plan follow-up visits on a more individualized basis. A recent study has summarized methods of assessing the quality of smart phone health-related apps and proposed a set of criteria that can used during the developmental stages of such apps to optimize the desired outcome [20].

India spearheading the digital movement records the second highest smart phones sales globally [21]. This statistic can be exploited effectively to increase health related awareness and disease follow up and thus bridge the gap, in a diverse country like

India where a huge and disproportionate gap still exists between the patient and care providers, especially in conditions associated with medical emergencies with high mortality, like cardiology.

The limitation of our study includes a small sample size and a short follow up. However, it provides a firm platform to develop and study such app based systems not only for an enhanced patient satisfaction but also to potentially access cost effectiveness and optimal utilization of health care services.

5. Conclusion

An app based system coupled with routine hospital based follow up of patients who had undergone PCI following an ACS event, shows higher satisfaction rate and comparable clinical outcome when compared to traditional hospital based follow up protocol alone. It has a high acceptance rate in an Indian population and thus this system should be explored further to optimize long term patient care.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ijcha.2021.100832>.

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