Original Articles

Management of acute coronary syndromes in secondary care settings in Kerala: Impact of a quality improvement programme

D. PRABHAKARAN, P. JEEMON, P. P. MOHANAN, U. GOVINDAN, Z. GEEVAR, V. CHATURVEDI, K. S. REDDY

ABSTRACT

Background. *Evidence-based therapies that have been shown to improve outcomes in acute coronary syndromes (ACS) are often underused in clinically eligible patients. We evaluated the impact, efficacy and acceptability of a quality improvement programme to manage ACS.*

Methods. *A well-defined geographical area was identified and a situational analysis done. All physicians in the area, who were actively involved in the detection and management of ACS, were invited to participate in the quality improvement programme. The programme involved the use of a service delivery package which consisted of standard admission orders and patient-directed discharge instructions. Concurrently, health education in the community to promote self-detection, self-administration of aspirin and self-referral were carried out. All participating physicians were asked to register consecutive cases of ACS (20 each) presenting to their clinics before and after the intervention programme. The pre- and post-intervention data were compared.*

Results. *The use of aspirin at discharge increased from 89.7% to 96.8% ($p<0.05$) and that of heparin from 57.6% to 66.3% ($p<0.05$). The use of beta-blockers increased from 48.6% to 63.4% ($p<0.05$) and that of lipid-lowering therapy from 74.1% to 96.3% ($p<0.05$). There was a significant reduction in the use of calcium channel blockers from 21.6% to 8.1% ($p<0.05$). The time to thrombolysis decreased significantly (median difference of 54 minutes, $p<0.05$) after the intervention programme.*

Conclusion. *Structured quality improvement programmes aimed at both patients and providers can be successful in secondary care settings of developing countries.*

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Centre for Chronic Disease Control, New Delhi 110016, India
P. JEEMON
All India Institute of Medical Sciences, New Delhi 110029, India
D. PRABHAKARAN, V. CHATURVEDI, K. S. REDDY
Department of Cardiology
Trichur Cardiac Club, Sopanam, Punkunnam, Trissur, Kerala, India
P. P. MOHANAN, U. GOVINDAN, Z. GEEVAR
Correspondence to K. S. REDDY, President, Public Health Foundation of India, PHD House, Second Floor, 4/2 Sirifort Institutional Area, August Kranti Marg, New Delhi 110016; *ksreddy@ccdcindia.org*

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INTRODUCTION

Acute coronary syndromes (ACS) continue to be a major contributor to mortality and morbidity in developing countries due to cardiovascular diseases (CVD).[1] Survival following ACS can be improved by providing prompt, acute care and evidence-based secondary preventive therapies.[2–8] Several studies emphasize the importance of early initiation of treatment for improving survival.[9–11] For example, in developing countries, it has been estimated by Gaziano that giving thrombolytic agents in <6 hours reduces the incremental cost per quality-adjusted life year (QALY) gained to around US$ 500 as compared with more than US$ 1200 per QALY gained if given after 6 hours.[12] However, considerable barriers exist in the optimal management of patients with ACS.[13] A study by WHO on the prevention of recurrence of myocardial infarction and stroke in developing countries including India reported underutilization of evidence-based, cost-effective and appropriate medications.[14] Several quality improvement studies in developed countries have shown that a comprehensive quality improvement programme (QIP) using targeted educational interventions, creation of quality standards and regular performance feedback are required to achieve sustained improvements in care.[15] The Cardiac Hospitalization and Atherosclerosis Management Program (CHAMP),[16] designed to encourage compliance with guidelines for secondary prevention after ST elevation myocardial infarction (STEMI), has shown dramatic improvements in the use of aspirin, beta-blockers, angiotensin-converting enzyme (ACE) inhibitors and statins. Similar studies have shown improvements in increased use of guideline-recommended, evidence-based therapies.[17,18] To the best of our knowledge, all these studies have been done in tertiary care settings.

We studied the impact of a comprehensive QIP in the detection and management of ACS in secondary healthcare settings, in improving 'symptom-to-door time' (SDT) and 'door-to-needle time' (DNT), provision of appropriate acute care and use of evidence-based secondary prevention medications in a large town in southern India.

METHODS

Setting

A well-defined geographical area comprising Trichur, Palaghat and Malappuram districts of Kerala, India was identified for QIP. Kerala is well known for the concept of good health at low cost.[19,20]

The identified area has a population of about 300 000 as per the estimates of the 2001 census. A total of 40 secondary care hospitals/nursing homes in this area had basic facilities for the management of patients with ACS. Nursing homes in Kerala are largely secondary care facilities staffed by physicians, surgeons, nurses and other paramedical employees catering generally to 20–100 in-patients. We made an initial assessment by reviewing the hospital admission registers and found that in a month an average of 400–500 ACS cases register with these hospitals/ nursing homes. We approached all the physicians who worked in these hospitals and treated patients with ACS. Thirty-four of them (85%) agreed to participate in the study.

Development of study tools

Initially, a survey was conducted, using a self-administered, structured questionnaire among primary and secondary care physicians in Kerala. The study units were nursing homes in the selected area and the main physician or the chief medical officer of the organization was asked to complete the questionnaire. A total of 132 nursing homes in Kerala (40 from the selected area) participated in this survey (response rate: 75%). This survey was helpful in assessing the existing practices of primary and secondary care physicians in the management of ACS. Following this, a single-page, structured proforma was developed and was used to register cases of ACS.

The study was conducted in 3 different phases—pre-intervention, intervention and post-intervention. The sample size planned for the study was 500 patients with ACS both in the pre- and post-intervention phases to demonstrate significant changes in the treatment pattern.

Pre-intervention phase (June 2005–October 2005)

All the participating physicians were asked to register consecutive patients with ACS (20 each) presenting to their clinic. The proforma was explained to all the physicians and regular feedback was sent to them on quality and completeness of data collection. Informed consent was taken from the patients before enrolment for the study. Confidentiality of the data was maintained by assigning a registration number for each patient and concealing their names.

Intervention phase (November 2005–February 2006)

The intervention phase mainly involved the use of a service delivery package and formal education of healthcare professionals in the detection and optimal management of ACS. Continuing medical education (CME) programmes were conducted as panel discussions for the physicians (rate of participation: 90%–100%) who were involved in providing care to patients with ACS. The service delivery package comprised standard admission orders and patient-directed discharge instructions, which were finalized at the beginning of the intervention phase by a focus group discussion among the entire group of participating physicians.

The admission order consisted of obtaining a baseline risk assessment involving detection of ACS (diagnosis by ECG, use of cardiac enzymes). Aspirin 325 mg was recommended at the time of initial presentation (if not received already) with a maintenance dose of 150 mg per day. Beta-blockers were recommended, unless contraindicated, to manage anginal symptoms, arrhythmias and control of blood pressure in all patients with ACS. ACE inhibitors were recommended in all patients with heart failure and also to manage high blood pressure in other patients unless contraindicated. Statins were recommended in all patients, irrespective of their low-density lipoprotein (LDL) cholesterol levels. Mandatory drugs at discharge (in the absence of contraindications) included aspirin 150 mg daily, beta-blockers, ACE inhibitors and statins. Irrespective of the standard admission and discharge orders, the final decision to initiate therapy was taken by the treating physician.

Training sessions were also conducted for 45 non-physician healthcare providers from various healthcare settings within the region for early detection and referral. Concurrently, health education programmes were carried out in the community to promote self-detection, self-administration of aspirin and self-referral. Health education classes were conducted at several locations (various community organizations, outpatient clinics, etc.) within the given geographical area. All electronic and print media were used to spread these messages.

Post-intervention phase (March 2006–May 2006)

All 34 participating physicians were again asked to register consecutive cases of ACS (20 each) presenting to their clinic during this period. The same structured proforma used in the pre-intervention phase was used in this phase too.

Coordination of activities

A coordinator was appointed at the local coordinating centre (LCC) and he worked under the supervision of an experienced cardiologist (PPM). The coordinator personally visited all the physicians at their place of practice and collected the completed proformas. The investigator at the LCC verified the first 100 proformas in the pre-intervention phase with available medical records. All inconsistencies in findings were discussed with the physician involved and resolved by consensus. Subsequently, the coordinator checked the consistency of the remaining completed proformas with the medical records. The data collected on the proforma were entered into a data entry software (Microsoft Access used as both front end and back end) exclusively developed for the study. The data were then saved as a 'comma separated file' and analysed using SPSS for Windows software. In the initial analysis of pre-intervention phase data by the national coordinating centre, we found some missing fields with regard to 'Killip class' and 'tobacco use'. Therefore, we requested the LCC investigator to verify all the proformas in the post-intervention phase with available medical records. All the identified missing data fields and inconsistencies with source data were discussed with the physician involved and resolved by consensus.

Definitions

'Symptom to door time' (SDT) was defined as the time difference between the onset of symptoms and primary contact with a healthcare system equipped to manage these diseases. 'Door to needle time' (DNT) was defined as the time difference between arrival at a hospital and initiation of thrombolysis in eligible STEMI cases. 'Time to thrombolysis' (TTT) was defined as the time difference between the onset of symptoms and initiation of thrombolysis (i.e. TTT=SDT+DNT).

Statistical analysis

Descriptive and analytical statistics were used to analyse the data. Percentages were used to describe the categorical variables and mean/medians were used for continuous variables. Mann–Whitney U test was used for comparison of medians and Chi-square test for comparison of proportions. Two-sided 'p' value <0.05 was taken as statistically significant.

RESULTS

Characteristics of the study population

A total of 629 patients with ACS were registered in the pre-intervention phase and another consecutive 403 patients with ACS were registered in the post-intervention phase. Their mean age was 58.2 years. Eighty-four per cent of the patients were <70 years of age. The overall prevalence rate of tobacco smoking was 44.5%, prevalence of hypertension was 42% and diabetes was reported in 42% of patients. Thirteen per cent of patients had a past history of myocardial infarction (MI).

Comparison of of the pre- and post-intervention groups

The two groups were similar in several aspects (Table I). There were no significant differences in the mean age, prevalence of tobacco smoking, hypertension, diabetes mellitus and history of previous MI between the two groups. The percentage of STEMI patients in both groups was also comparable. However, the percentages of women and overweight patients were significantly lower (21.6% and 24.5%, respectively; p<0.05) in the post-intervention group as compared with that in the pre-intervention group (28.9% and 39.4%, respectively; p<0.05).

Changes in practice patterns

At the time of admission. The use of aspirin and beta-blockers at the time of hospital admission changed significantly after the intervention phase (Table II). There were no major differences in other forms of medical therapy at the time of admission (use of calcium channel blockers, ACE inhibitors and statins) before and after the intervention. Twenty-two per cent of the patients were referred by a non-physician healthcare provider in the post-intervention phase as compared with 10% before the intervention.

During the hospital stay and at discharge. Medical therapy during hospital stay changed significantly after the intervention (Table III). We observed a significant increase in the use of aspirin, anticoagulants, beta-blockers and lipid-lowering therapy. The use of aspirin increased from 89.7% to 96.8% (p<0.05) and that of heparin from 57.6% to 66.3% (p<0.05). The use of beta-blockers increased from 48.6% to 63.4% (p<0.05) and that of lipid-lowering therapy from 74.1% to 96.3% (p<0.05). Also, there was a significant reduction in the use of calcium-channel blockers from 21.6% to 8.1% (p<0.05). The use of alpha-receptor blockers and ACE inhibitors did not change after the intervention.

Changes in SDT and DNT. The median SDT (Table IV) significantly reduced from 159.5 minutes to 116.8 minutes after the intervention (p<0.05). When SDT was stratified into 4 groups, we observed that most of the time gained was in patients presenting after 2 hours of onset of symptoms in the post-intervention group.

There was no significant difference in the rate of thrombolytic therapy in the pre-intervention (54.2%, 95% CI: 51.4–57.8) and post-intervention groups (56.6%, 95% CI: 52.1–59.6). The median time taken to initiate thrombolysis (DNT) also decreased significantly (p<0.05) from 33.3 minutes in the pre-intervention phase to 22.3 minutes in the post-intervention phase (Table V). When DNT was stratified into 3 groups, we observed that a

TABLE I. Clinical characteristics of the patients

Characteristic	Pre-intervention (2005) (*n*=629)	Post-intervention (2006) (*n*=403)
Mean (SD) age in years	58.5 (11.7)	57.6 (11.8)
Median years of schooling (IQR)	9.0 (4–11)	8.4 (4.3–11.2)
Women	28.9 (26.0–31.8)	21.6* (16.8–24.1)
Smoking	42.4 (38.1–45.4)	47.6 (43.8–49.9)
Overweight	37.4 (34.9–39.6)	24.5* (20.1–27.1)
Hypertension	44.4 (41.9–46.7)	38.5 (36.2–42.3)
Diabetes mellitus	40.7 (38.3–43.1)	44.8 (41.9–46.5)
Previous myocardial infarction	14.3 (12.9–15.9)	10.7 (8.7–13.1)
ST segment elevation myocardial infarction	62.5 (59.9–64.3)	59.3 (56.8–63.1)

Values in parentheses are 95% confidence intervals unless specified
*Two-tailed p<0.05 Overweight body mass index ≥25 IQR interquartile range

TABLE II. Treatment rates at admission

Treatment	Pre-intervention (2005) (*n*=629) % (95% CI)	Post-intervention (2006) (*n*=403) % (95% CI)
Aspirin	24.8 (22.2–26.4)	32.5* (30.1–34.5)
Nitrates	18.4 (16.9–19.8)	14.9 (12.7–17.3)
Beta-blockers	9.4 (7.9–10.8)	19.4* (17.1–21.5)
Calcium-channel blockers	4.6 (4.0–5.6)	4.0 (3.0–5.2)
ACE inhibitors	7.8 (6.7–8.6)	5.5 (4.7–6.9)
Lipid-lowering agents	12.4 (10.2–13.2)	10.3 (8.8–12.9)

* Two-tailed p<0.05 ACE angiotensin-converting enzyme

TABLE III. Treatment during hospital admission

Treatment	Pre-intervention (2005) (*n*=629) % (95% CI)	Post-intervention (2006) (*n*=403) % (95% CI)
Aspirin	89.7 (85.9–92.1)	96.8* (93.1–99.3)
Anticoagulants	57.6 (54.2–59.8)	66.3* (60.2–69.9)
Calcium-channel blockers	21.6 (18.1–24.2)	8.2* (6.9–9.3)
Beta-blockers	48.6 (46.2–50.2)	63.4* (60.2–66.6)
ACE inhibitors	36.4 (31.9–39.4)	38.8 (34.2–43.1)
ARBs	5.2 (3.7–6.4)	3.0 (2.0–4.1)
Lipid-lowering agents	74.1 (71.9–76.6)	86.3* (80.9–89.2)

* Two-tailed p<0.05 ACE angiotensin-converting enzyme ARB angiotensin receptor blocker

TABLE IV. Comparison of symptom-to-door time (SDT) before and after the intervention

Symptom-to-door time (in minutes)	Pre-intervention (2005) (*n*=629)	Post-intervention (2006) (*n*=403)
Median	159.5	116.8*
0–120	58.2%	55.6%
120–240	25.9%	31.3%
240–360	7.2%	9.9%
>360	8.7%	3.2%

* Two-tailed p<0.05

TABLE V. Door to needle time (DNT) and time to thrombolysis (TTT) in patients with ST elevation myocardial infarction (STEMI)

Time (in minutes)	Pre-intervention (2005) (*n*=393)	Post-intervention (2006) (*n*=239)
Door-to-needle time		
Median	33.3	22.3*
<30	43.2%	71.6%*
30–60	50.3%	28.2%
>60	6.5%	0.23%
Time to thrombolysis		
Median	193.0	139.0*
0–120	45.3%	52.1%
120–240	31.0%	32.0%
240–360	18.3%	10.0%
>360	5.4%	5.9%

* Two-tailed p<0.05

majority of patients (71.6%) received treatment in the first 30 minutes in the post-intervention group as compared with 43.2% in the pre-intervention group. TTT also decreased significantly (median difference of 54 minutes, $p<0.05$). Additionally, when TTT was stratified into 3 groups, we observed that 52.1% of STEMI patients received thrombolysis within the first 2 hours after the onset of symptoms in the post-intervention group as compared with 45.3% in the pre-intervention group, and 67% within 3 hours in the post-intervention group as compared with 56% in the pre-intervention group.

DISCUSSION

Our study demonstrates the usefulness of a comprehensive QIP in the detection and management of ACS in secondary care settings. In general, QIP effectively improved the best available evidence-based treatment practices and adherence to a common treatment protocol. Similar significant improvements in evidence-based treatment practices have been reported in many other studies but all these have been in tertiary care settings.[16–18] These studies have confirmed that well-designed quality improvement initiatives can overcome barriers that limit the implementation of available guidelines for the management of patients with ACS. However, most of these studies were too small to estimate the effect of improved care on patient outcomes. A few larger studies have shown long term mortality benefits associated with increased use of evidence-based therapies or improved adherence to guideline-based care.[21,22] Our study was conducted in secondary care settings which are generally the first level of contact in case of an acute coronary event.

To the best of our knowledge this is the only study conducted in a developing country setting. It has shown improvements in SDT and rate of self-administration of aspirin immediately after the onset of an acute event. The Assessment of Capacity for Control of CVD study,[23] a multicountry, multicentre study on assessment of composite community capacity for the prevention and control of CVD and diabetes in developing countries, clearly showed that knowledge of use of aspirin in suspected cases of ACS was strikingly low among both patients as well as healthcare providers. Therefore, our study has contextual relevance to developing country settings where knowledge of ACS and correct management practices are inadequate. Our study has the potential to be replicated in other states of India and other developing countries.

DNT also reduced significantly after the intervention. It was reasonably good even in the pre-intervention phase and was comparable with that in developed countries. These findings may be related to the uniqueness of Kerala which has the best health indices in India. It is also well connected by roads and access to healthcare is better than that in many other states in India.[20] However, our results can be generalized to several parts of India which have achieved similar levels of health indices as Kerala.

A meta-analysis of 6 randomized controlled trials involving 6434 patients on mortality and pre-hospital thrombolysis for STEMI has shown a similar saving of 58 minutes in TTT in the pre-hospital group and a significant decrease in all-cause hospital mortality (OR=0.83; 95% CI: 0.7–0.98).[24] Boersma *et al*. pooled the data from 22 RCTs that compared fibrinolytic therapy with placebo or control and proposed the concept of 'golden hour', with the largest survival benefits in the first 2 hours (65 lives saved per 1000 patients treated in the first hour and 37 lives saved per 1000 patients treated in the second hour) and a non-linear decline in survival benefit thereafter.[10] The time of 54 minutes gained in our study in terms of TTT is similar to these results. While pre-hospital thrombolysis is costly and a difficult concept to implement in India or any other developing country setting, what is remarkable is that we were able to achieve similar gains as pre-hospital thrombolysis. We believe that such a significant reduction in TTT has the potential to improve clinical outcomes in patients with ACS especially in developing countries such as India where the highest rate of mortality from ACS is reported.[25]

We also believe that the observed benefits in our programme result from the comprehensive nature of the programme which targeted all the stakeholders (physicians, non-physician healthcare providers and community members at risk for developing ACS). Though guidelines for the management of ACS are widely available, they are seldom followed in India. In the initial survey involving 132 nursing homes in Kerala, we noted some barriers to the implementation of guideline-based care in the management of ACS. Lack of physician knowledge and awareness, familiarity, agreement with practice guidelines and uncertainty about the relevance of treatment recommendations for diverse patients in actual clinical practice are often suggested as impediments to the implementation of guideline-based care. Rather than relying only on guidelines, it would be useful to consider such low cost programmes in similar settings.

Limitations

The number of individuals in the post-intervention phase was less than the expected number as we thought we would get at least 500 individuals. The seasonal variation in frequency of events and shorter duration of the study in the second half could explain this difference. The demographic and clinical characteristics of the 2 groups (pre-intervention and post-intervention) in this study were similar in many aspects. However, the proportion of women and overweight subjects were less in the post-intervention phase. The sex difference could be by chance and might have influenced the proportion of overweight subjects as well.

As there was no concurrent control group in the study design, one could argue that factors other than the elements of comprehensive QIP may have influenced the treatment rate. However, the short duration of our study and no new findings in the evidence-based therapy during the programme also support our argument. Our study findings may be different in clinical settings of other states in India, as Kerala is different from the rest of the country. Thus, our study could be generalized to many other parts of India with a similar literacy rate. The post-intervention phase was immediately after the intervention phase and it was of a shorter duration. Therefore, we could not assess the long term impact of the programme on practice patterns. We also did not assess the impact of the changes in practice patterns on clinical outcomes. This will need to be further assessed in a large follow up study involving more patients.

Conclusion

Improvements in evidence-based treatment practices were observed after the comprehensive QIP. The TTT dropped significantly (median difference of 54 minutes, $p<0.05$) after the intervention programme. Additionally, when TTT was stratified into different groups, we observed that 52.1% of STEMI patients received thrombolysis within the first 2 hours of the onset of symptoms in the post-intervention group as compared with 45.3% in the pre-intervention group. Such a significant reduction in TTT has the potential to improve clinical outcomes in patients with ACS.

A similar evaluation of ACS treatment may help to guide efforts designed to promote evidence-based care and ultimately

determine the effect of widespread implementation of practice guidelines on clinical outcomes. The methods used to implement this programme are readily available and could be easily implemented in any similar hospital and community setting. The quality improvement and monitoring of adherence to practice guidelines should be taken as components of optimal clinical practice in the detection and management of ACS in similar settings.

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Contributions

K. S. Reddy and D. Prabhakaran developed the concept of this paper. P. P. Mohanan supervised the study in Kerala and finalized the dataset. P. Jeemon compiled, cleaned and analysed the data. He compiled the results and wrote the first draft of this paper. All other authors contributed further and modified the paper.

Conflicts of interest

None declared

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National coordinating centre (NCC)

K. S. Reddy, D. Prabhakaran, P. Jeemon, V. Chaturvedi

Local coordinating centre (LCC)

P. P. Mohanan, U. Govindan, Z. Geevar, S. Sreejith

Participating investigators

Shajan Chakko (Irinjalakkuda), Rajeev ((Irinjalakkuda), Madhu (Irinjalakkuda), Udayabhanu (Koorkencherry), Shojan Augastin (Trissur), Poulose George (Trissur), Santha Kumar (Shoranur), Joshy Thomas (Kunnamkulam), G. B. Chungath (Kunnamkulam), Rajesh Krishnan (Trissur), Damodaran (Chavakkad), Sasikumar (Chavakkad), Jose Ukkan (Kodungallur), Shelly (Vadanappally), Chandrasekaran (Koorkencherry), Willson (Koorkencherry), Gopinadhan (Trissur), V. M. Haridas (Trissur), Gopalakrishnan (Irinjalakkuda), A. K. Mathew (Ollur), Ramaswami (Palakkad), M. A. Siar (Palakkad), B. Gopal (Palakkad), Veera Raghavan (Palakkad), Muraleedharan (Palakkad), Boby Manual (Palakkad), N. M. Arun (Palakkad), Rajeevan (Pattambi), V. K. Sadasivan (Palakkad), Unnithan (Ottapalam), Rajkumar (Ottapalam), Shanmughan (Ottapalam), Narayanan (Puthanpalli), Narayanan (Edapal).