Management of Acute Coronary Syndromes (ACS) in secondary care settings in Kerala, India: Impact of a quality improvement programme

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Background

Acute Coronary Syndromes (ACS) consists of mainly acute ST-segment elevation myocardial infarction (STEMI), non ST-segment elevation myocardial infarction (Non-STEMI) and unstable angina (UA). Despite the advances in detection, treatment and management of ACS, it continuous to be a significant contributor to mortality and morbidity attributed to Cardiovascular Diseases (CVD), even in developing countries. Development of ACS is recognized as an acute fatal event in approximately one third of the patients. Additionally, almost half of these deaths occur within one hour of the event and usually the reaction time is very short.[3] Prompt and early detection of ACS and immediate initiation of therapy are therefore warranted in reduction in mortality and morbidity due to ACS.

Large scale clinical trials performed during the last 1-2 decades have changed the treatment practices of ACS over the period of time. The evidence based management strategies evolved from these studies had guided to the development of clinical practice guidelines for detection and management of ACS. However, significant barriers exist in the implementation of these guidelines in diverse health care settings especially in low resource countries. This has further limited the adoption of widespread use of beneficial evidence based therapies.

Several quality improvement studies have shown that comprehensive quality improvement programme using targeted educational interventions, creation of quality standards and regular performance feedback are required to achieve sustained improvements in care. The Cardiac Hospitalisation and Atheresclerosis Management Program (CHAMP), designed to encourage compliance with guidelines for secondary prevention after STEMI, have shown dramatic improvements in the use of aspirin, beta blockers, ACE inhibitors and statins. Similar improvements in increased use of guideline recommended evidence based therapies have demonstrated in various other projects. Lower hospital mortality rates are documented with improved adherence to clinical practice guidelines in many long term ACS registries.

This study was particularly undertaken to assess the impact of a comprehensive quality improvement programme in detection and management of ACS in secondary health care settings on evidence based primary and secondary prevention medications utilization, ‘symptoms to door time’ and ‘therapy initiation time’.

Methods

Definitions

'Symptoms to door time' is defined as the time difference between onset of symptoms and primary contact with a health care system equipped to manage these diseases. 'Therapy initiation time' is the time taken to initiate thrombolysis therapy (time difference between arrival at the hospital and initiation of thrombolysis) in eligible STEMI cases.

The study was conducted in three different stages namely pre-intervention phase, intervention phase and post-intervention phase.

Pre-intervention phase (May 2006-Oct 2006)

A well defined geographical area comprising of Trichur, Palaghat and Malappuram districts of Kerala was identified for this program. A situational analysis was carried out and identified physicians at primary and secondary health care settings actively involved in detection and management of ACS. They were invited to participate in the main study. Altogether, 35 physicians agreed to participate in the study. All the participating physicians were asked to register consecutive cases of ACS (20 each) presented to their clinic. A single paged structured proformae was developed and this was used to register cases of ACS. The proformae was explained to all physicians and frequent feed back were sent to them on quality and completeness of data collection regularly. Informed consent was taken from the patient for registration of cases and sharing of data. Additionally, confidentiality of the data was maintained as cases were registered on the proformae by assigning a registration number. The shared database with other people involved in the project only contains the patient registration number.

Intervention phase (Nov 2006-Feb 2006)

Intervention phase mainly involved development of service delivery package and formal medical education in detection and optimal management of ACS for health care professional including all participating physicians. Training sessions were also conducted for 45 nurses and multi-purpose health workers at various health care settings within the region. This was followed by health education in the community to promote self detection, self administration of aspirin and self referral. Health education classes were conducted at various places and all electronic and print media were used to spread the message.

Standard admission orders and patient directed discharge instructions were discussed with all participating physicians and circulated among them. Almost all physicians involved in the study were actively participated in all related programs and the participation rate was very high. We have managed to bring together all 35 physicians for a panel discussion conducted during the intervention phase.

The admission order consisted of obtaining a baseline risk assessment involving detection of ACS (diagnosis by ECG, use of cardiac specific enzymes) and further risk stratification. Aspirin 325 mg was recommended at the time of initial presentation with a maintenance dose of 150 mg per day. Beta blocker therapy was recommended, unless contraindicated, to manage anginal symptoms, arrhythmias and control of blood pressure in all ACS patients. 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, especially those who are with LDL cholesterol of more than 100 mg/dl. Irrespective of the standard admission and discharge order, the final decision to initiate therapy was decided by the individual treating physician.

Post-intervention phase (March 2006-May 2006)

All 35 participating physicians were again asked to register consecutive cases of ACS (20 each) presented to their clinic during this period. The same structured proformae used in the pre-intervention phase was used in this phase also.

Coordination of activities

A coordinator was appointed at the coordinating centre and he worked under the supervision of the principal investigator. The coordinator had personally visited the entire physicians at their practice place and collected completed proformae. He manually checked the proformea through simple eye balling and sought the help of the participating physician or his/her representatives in filling any incomplete data fields.

Data analysis

Descriptive and analytical statistics were used in the analysis of data. For categorical variables percentages were used to describe the data and for continuous variables mean/median were used. Two sided 'p' value less than 0.05 is taken as statistically significant.

Results

Altogether, 629 ACS patients were registered in the pre-intervention phase and another consecutive 403 patients in the post-intervention phase. The mean age of the total cases was 58.2 years. Eighty percent of the cases were below the age of 68 years. The overall prevalence rate of tobacco smoking was 44.5% and that of use of other form of tobacco was 5.7%. Thirteen percent of cases had past history of myocardial infarction. The overall prevalence of hypertension and diabetes was 42% among study subjects. However, the two groups were similar with regard to a variety of baseline characteristics (table 1). There were no statistically significant differences between the two groups in terms of mean age, prevalence of tobacco smoking, hypertension, diabetes mellitus, previous MI and percentage of STEMI cases. The percentage of women, and overweight subjects

were significantly lower (21.6% and 24.5% respectively) in the post-intervention group compared to that in pre-intervention group (28.9% and 39.4% respectively).

As desired, medical therapy (use of aspirin and beta blockers) at the time of hospital admission has changed significantly after intervention (table 2). There were no major differences in other medical therapy at the time of admission (use of calcium channel blockers, ACE inhibitors and statins) before and after intervention. The mean symptom to door time was significantly reduced from 159.5 minutes to 117 minutes after the intervention.

Medical therapy during the course of hospital admission changed significantly after the intervention (table 3). We noticed significant increase in use of aspirin, anticoagulants, beta blockers, and lipid lowering therapy. Utilization rate of aspirin increased from 89.7% to 96.8% and that of anticoagulants increased from 57.6% to 66.3%. Beta blockers utilization rate was increased from 48.6% to 63.4% and that of lipid lowering therapy increased from 74.1% to 96.3%. Moreover, there was a significant reduction in use calcium channel blockers from 21.6% to 8.1%. This difference in medical therapy was achieved without significantly altering the utilization rate of alpha receptor blockers and ACE inhibitors.

There was no significant differences in the rate of thrombolysis therapy (54.2% and 56.6%) in the two groups (table 4). However, the time taken to initiate thrombolysis had dropped significantly from 33 minutes in the pre-intervention phase to 22 minutes in the post-intervention phase.

Discussion

In our study, we demonstrated that comprehensive quality improvements programme in detection and management of ACS could effectively improve best available evidence based treatment practices and adherence to a common treatment protocol. Involvement of other health care workers like nurses and multi-purpose workers in the comprehensive quality improvement programme also paid the dividend as evident in the significant reduction in symptoms to door time and increased utilization rate of aspirin even before reaching a health care set up in case of an acute event. This could be partly attributable to the extensive community based health education programmes in self detection, self administration of aspirin and self referral. The methods used to implement this programme are readily available and would be expected to be able to be implemented in any similar hospital settings and community.

Similar, significant improvements in evidence based treatment practices are reported in many other studies as well albeit with a difference in level of health care. This study was mainly conducted in secondary care settings and in most

instances they are the first level of contact in case of an acute event. Our findings have more value, considering this fact that it was implemented in secondary health care settings targeting physicians and not with experienced cardiologists in tertiary level settings. International or national clinical practice guidelines alone could not make any major impact in treatment practices in these health care settings because of multi-layered barriers. Lack of physician awareness, familiarity, agreement with practice guidelines and uncertainty about relevance of treatment recommendations for diverse patients in actual clinical practice are often suggested as impediments to implementation of guideline based care.[16] Additionally, the implementation of these guidelines require a certain level of expertise and facilities for treatment which often not present in low resource settings.

Probably this is the only one study showed improvements in 'symptoms to door time' and increased rate of self administration of aspirin immediately after the onset of an acute event. The *assessment of capacity for control of CVD* study, a multi-country, multi-centre study on assessment of composite community capacity for prevention and control of CVD and diabetes in developing countries, clearly showed that knowledge of use of aspirin for suspected ACS cases was strikingly low both among patients and health care providers. Therefore this study is very relevant in the developing countries settings and should be replicated in other states within the country and outside the country in similar health care settings.

The time taken to initiate thrombolysis therapy had also reduced significantly after the intervention. This would certainly have significant improvements in clinical outcomes in a country like India where highest rate of mortality from ACS is reported.

Limitations

As there was no concurrent control group in the study design, one could argue that factors other than the elements of comprehensive quality improvement programme may have influenced the treatment utilization rate though we argue otherwise. The short duration of the study and no major changes in the evidence based therapy in this duration of the programme also support our argument. The study 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 with very strict inclusion criteria.

Conclusion

Improvements in evidence based treatment practices were observed after the comprehensive quality improvement programme. This comprehensive evaluation of ACS treatment helped to guide efforts designed to promote evidence-based care and ultimately determined the effect of widespread implementation of practice guidelines on clinical outcomes. This study therefore suggests that

quality improvement and monitoring of adherence to practice guidelines should be considered components of optimal clinical practice in the detection and management of ACS.

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Table 1: Patients' Clinical Characteristics

Variable	Pre-intervention (2005) (n=629)	Post-intervention (2006) (n=403)
Age (in years + SD)	58.5 + 11.7	57.6 + 11.8
Women %	28.9	21.6*
Smoking %	42.4	47.6
Other form of tobacco %	7	3.7*
Overweight	37.4	24.5*
Hypertension	44.4	38.5
Diabetes mellitus %	40.7	44.8
Previous MI	14.3	10.7
STEMI	62.5	59.3
*2 tailed p<0.05 Overweight = Body Mass Index >=25 Previous MI = Previous Myocardial Infarction STEMI = ST segment Elevation Myocardial Infarction		

Table 2: Treatment rates at admission

Variable	Pre-intervention (2005) (n=629)	Post-intervention (2006) (n=403)
Aspirin %	24.8	32.5*
Nitrates %	18.4	14.9
Beta Blockers %	9.4	19.4*
Ca Channel Blockers %	4.6	4
ACE Inhibitors %	7.8	5.5
Lipid Lowering %	12.4	10.3
Symptoms to door time (Mean value in minutes)	159.5	116.8*
*2 tailed p<0.05 ACE = Angiotensin Converting Enzymes Ca Channel Blockers = Calcium Channel Blockers		

Table 3: Treatment during the course of hospital admission

Variable	Pre-intervention (2005) (n=629)	Post-intervention (2006) (n=403)
Aspirin %	89.7	96.8*
Anti-coagulants %	57.6	66.3*
Ca Channel Blockers %	21.6	8.2*
Beta Blockers %	48.6	63.4*
ACE Inhibitors %	36.4	38.8
ARBs %	5.2	3.0
Lipid Lowering %	74.1	86.3*
*2 tailed p<0.05 ACE = Angiotensin Converting Enzymes Ca Channel Blockers = Calcium Channel Blockers		

Table 4: Thrombolysis rate in STEMI cases and time taken to initiate therapy

Variable	Pre-intervention (2005) (n=393)	Post-intervention (2006) (n=239)
Thrombolysis	54.2	56.6
Time taken to initiate thrombolysis (mean value in minutes)	33.3	22.3*
*2 tailed p<0.05		

Admission order and discharge advise of ACS patients: ACS Trichur Project

On the basis of presenting symptoms of the patient, the patient should be classified as having typical, atypical or non-cardiac chest pain. In case of atypical chest pain, chewable aspirin (325 mg, if already not on aspirin) and isosorbide dinitrate should be given. Following these measures, an ECG should be done, based on which the patient should be further categorized into having either ST elevation myocardial infarction (STEMI) or ST/non ST elevation unstable angina or a normal ECG.

In case of a STEMI, the patient should be shifted to a coronary care unit (CCU) within 30 minutes for further management and thrombolytic therapy (streptokinase) in the standard dose. If the CCU is further away, the patient should be given streptokinase at the place of presentation and then shifted to the CCU.

In the event of ST/non-ST elevation unstable angina, the patient should be given injectable heparin (5000 units by bolus over 30 minutes + aspirin 150 mg) and then shifted to the CCU where following blood enzyme analysis, standard care should be provided. In case of a normal ECG, the patient should be monitored for continuing chest pain and if patient is in the high risk category, should be shifted to CCU. In the absence of pain and if patient is low risk, repeat an ECG an hour later. If STEMI is detected, shift the patient to CCU. In case of a normal ECG, the patient should undergo risk stratification.

Beta-Blockers

Oral beta-blocker therapy should be administered promptly to those patients without a contraindication, irrespective of concomitant fibrinolytic therapy.

Contraindications: Heart rate <60/min, SBP< 100 mmHg, Moderate-severe heart failure, Pulse Rate >0.24, 2nd/ 3rd degree heart block, COPD

ACE Inhibitors/ ARB

An ACE inhibitor should be administered orally within the first 24 hours of STEMI to patients with anterior infarction, pulmonary congestion, or LVEF less than 0.40, in the absence of hypotension (systolic blood pressure less than 100 mm Hg or less than 30 mm Hg below baseline) or known contraindications to that class of medications. ARBs can be administrated in patients intolerant to ACE inhibitors.

Low molecular weight heparin (LMWH)

LMWH reduced mortality in patients with STEMI irrespective of whether thrombolysis received or not. Therefore LMWH should be considered as and when necessary

Pharmacologic therapy	
Patients without ST segment elevation	
Aspirin	All patients should be given aspirin (325 mg initial dose if not on aspirin followed by 150 mg daily) to be chewed
Clopidogrel	Patients at intermediate and high risk should also be given 300 mg of clopidogrel
Low molecular weight heparin	Patients at intermediate and high risk should receive the first dose of a low molecular weight heparin (1 mg/Kg sc)
Nitrates	(in patients with systolic BP $\geq$ 100 mm Hg) (for patients with ongoing pain) Capsules of glyceryl trinitrate 0.4 mg S/L or Isosorbide dinitrate tablets
Patients with ST segment elevation	
Aspirin	All patients should be given aspirin (325 mg initial dose if not on aspirin followed by 150 mg daily) to be chewed
Clopidogrel	Patients at intermediate and high risk should also be given 300 mg of clopidogrel
Nitrates	In patients with systolic BP $\geq$ 100 mm Hg (for patients with ongoing pain)
Streptokinase infusion	In patients with ST segment elevation, Streptokinase infusion (1.5 MU) should be initiated in the PHC/ "chest pain outpost" before transfer to the nearest CCU

Mandatory drugs at discharge (in the absence contra indication):

1. Aspirin 150 mg daily
2. Beta adrenergic receptor blockers
3. ACE inhibitors
4. Statins

Kindly note that the treatment order is based on evidence based cost-effective practices. However, the final decision to initiate therapy is with the individual treating physician. Participation in this programme is not a hindrance to make any amendments to treating individual cases based upon your thoughts.