Cardiac Pacemakers (#CAG-00063N)

Inclusion Table

Study ID	Description	Type of Study	Results/ Conclusion	HCFA Comments
Update: ACC/AHA Guidelines for the Management of Patients With Acute Myocardial Infarction.1999.	This is a set of guidelines jointly established by the American College of Cardiology and the American Heart Association. These guidelines, "Include the most significant advances that have occurred in the management of patients with AMI from 1996-1998."	Clinical Guidelines	Survivors of myocardial infarction are treated with long-term beta-blockers provided that they do not have one or more of the following relative contraindications: • Heart rate less than 60 bpm, • Systolic arterial pressure less than 100 mm Hg, • Moderate left ventricular failure, • Signs of peripheral hypoperfusion, • PR interval greater than 0.24 second, • Second- or third-degree atrioventricular (AV) block, • Severe chronic obstructive pulmonary disease, • History of asthma, • Severe peripheral vascular disease, or • Insulin-dependent diabetes	Not applicable

			mellitus.	
ACC/AHA Guidelines for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices.1998.	This is a set of guidelines jointly established by the American College of Cardiology and the American Heart Association. These guidelines update the 1984 and 1991 previously published guidelines concerning cardiac pacemakers and antiarrhythmia devices.	Clinical Guidelines	Sinus Node dysfunction with documented symptomatic bradycardia, including frequent sinus pauses that produces symptoms. In some patients, bradycardia is iatrogenic and will occur as a consequence of essential long term drug therapy of a type and dose for which there are no acceptable alternatives.	Class I Level Evidence C Class I recommendation means that there is evidence and/or general agreement that beta-blockers are beneficial, useful, and effective for the post-MI patient without contraindications. Level C evidence is a consensus opinion of experts.
B-Blocker Heart Attack Trial Research Group. 1982.	The B-Blocker Heart Attack Trial (BHAT) tested if the regular administration of propranolol hydrochloride to patients, who had experienced at least one MI, would experience a reduction in mortality (from all causes) during a 2-4 year period.	Randomized	There was excellent compatibility between the control and treatment groups. Overall, propranolol reduced mortality by 26%. The treatment was effective for patients who had more than one MI, a single MI with complications (i.e. congestive heart failure) or a single uncomplicated MI.	Patients with contraindications, such as, marked bradycardia, were excluded from the study.
CIBIS-II Investigators and Committee. 1999.	This study was designed to test the results of CIBIS I. The initial trial demonstrated a non-significant trend towards a 20% lower mortality in the treatment group (bisoprolol) and 30% fewer admissions to hospital for worsening heart failure.	Randomized	CIBIS-II was stopped early because bisoprolol showed a significant mortality benefit. All-cause mortality was lower for those treated with bisoprolol (11.8%) compared to the placebo group (17.3%).	The mean age of patients was 61. The authors suggests that more information is needed concerning treatment options for old and very old patients.
Dreifus, Leonard S. 1983.	This is a review of cardiac pacing for patients with conditions such as bradycardia and sick sinus syndrome.	Review	Pacemakers play a role for symptomatic patients, however, excessive use needs to be avoided. Prognosis for asymptomatic patients is usually favorable without pacemaker implantation.	The article briefly mentions the use of pacing for patients treated with a combination of drugs to suppress tachycardias. The focus of the article was on symptomatic patients.
HCFA's Acute Myocardial	This project seeks to lower the one-year	Not	Administration of aspirin, beta-blockers, ACE-	No comments were made concerning the

Infarction National Project Overview (originally published as part of HCFA Pub.No.10156)	mortality for Medicare beneficiaries post MI. Project objectives include increasing the administration of aspirin, beta-blockers and ACE-inhibitors.	applicable	inhibitors and smoking cessation improve survival.	project's impact on the asymptomatic population.
Frishman, William H, Furberg, Curt D, Friedewald, William T. 1984.	This is a review concerning beta-blocker therapy for survivors of acute myocardial infarction. topics covered include: the long-term use of beta-blockers, mechanisms of benefit, clinical use and dosages.	Review	Not applicable	The authors report that up to 20% of MI survivors have absolute or relative contraindications to beta-blockade. The remaining patients may benefit from this therapy.
Geddes, JS. 1982.	A small population of patients with ventricular arrhythmias were treated with beta-blockers combined with pacemakers. This treatment was provided to investigate methods of controlling arrhythmias.	Case series	Beta-blockers, in addition to pacing, are an effective combination for managing arrhythmias. There were two groups of patients studied: one group consisted of 36 bradycardic individuals who received temporary or permanent pacing. Of these patients, 67% experienced benefit. The second group consisted of 14 patients with arrhythmias, of which 10 patients experienced positive outcomes.	In the first group, 27 patients were implanted with a permanent pacemaker. Eight of these patients, or 30%, relapsed and experienced severe symptoms or MI.
Gottlieb, Stephen S, et al. 1998.	Beta-blockers improve survival for post MI patients. Physicians hesitate to prescribe beta-blockers to older individuals, those with chronic pulmonary disease, left ventricular dysfunction, or non-Q-wave myocardial infarction. It is unknown if these patients benefit from beta-blocker therapy.	Retrospective cohort	Patients post MI, with no other complications experienced a 40% reduction in mortality. Mortality was also reduced by 40% in patients with non-Q-wave infarction and those with chronic obstructive pulmonary disease.	It is possible that the patients who received beta-blockers were healthier than those who did not.
Hjalmarson, Ake. 1997.	This article reviews the literature and reports the impact of beta-blocker therapy in preventing cardiac death during acute MI and the post MI.	Review	Pooling the data from 24 long-term beta-blocker studies reveals a 34% reduction in the risk of cardiac death.	There is little information concerning patient selection for each trial. It is unknown if the patients included in these trials are reflective of the asymptomatic population of patients targeted in the

				coverage request.
Krumholz, Harlan, et al. 1998.	This article says that beta-blockers have been demonstrated to be an effective treatment for post MI patients, however they are underutilized in the elderly. This study attempts to describe the contemporary national pattern of beta-blocker usage among patients 65 and older with an AMI who are discharged from the hospital. It also uses the same database as the Gottlieb study.	Retrospective cohort	There was a great deal of variation by state concerning beta-blocker treatment. The New England region had higher rates of beta-blocker usage than other areas of the country. There was a 14% lower risk of mortality for those on beta-blockers one year after discharge. Elderly patients treated with beta-blockers at hospital discharge had a better survival rate.	Patterns of beta-blocker use after discharge could not be monitored, therefore the long-term pattern of use may be misclasified. The researchers ability to ascertain contraindications to beta-blockers was hindered by information in the charts. The study sample was hospitalized in 1994 and 1995 and there may improvements in the quality of care.
McCormick, Danny, et al. 1999.	This study attempts to examine trends in and determinants of receipt of aspirin, beta-blockers and lipid-lowering agents for post MI patients before hospitalization for reinfarction.	Case series	Over this 10-year study, there was an increase in the use of aspirin and lipid-lowering medications. There were only modest changes in beta-blocker use. Clinical factors, such as contraindications, were factors, however, non-clinical factors, such as age and sex were also relevant.	Data was unavailable to measure the impact contraindications had on medication use.
Mehta, Rajendra, et al. 1998.	The authors reviewed articles from January 1980 to August 1997, which discussed secondary prevention for individuals post MI.	Review	Efforts need to be made to decrease the chances of reinfarction. Patients post MI should be administered beta-blockers and aspirin.	High-risk patients without contraindications benefit the most from beta-blocker treatment.
Michihiro, Suwa, Takahide, Ito, Yoshiaki, Otake, et al. 1998.	This study was conducted in order to determine if beta-blockers were effective in patients with nonischemic dilated cardiomyopathy and bradyarrhythmias supported by pacemaker implantation. Bradyarrhythmias include: atrioventricular block, sick sinus syndrome and atrial fibrillation and slow heart rate.	Case series	Out of the 56 patients without bradyarrhymias, 42 responded to bisoprolol. The efficacy was reported as 75%. Of the 7 patients with bradyarrhythmias, who had a pacemaker implanted, 5 responded to bisoprolol. The efficacy rate was 71%. The authors report that there is no clear distinction between the groups.	The population of patients with bradyarrhythmias was too small (7) to report and sort of substantial conclusion. It is misleading to conclude that beta-blocker therapy, with pacemaker implantation, is beneficial for these patients.
National Cholesterol Education Program Expert	This is a report that provides updated recommendations for	Report	Not applicable	Not applicable

Panel. 1994.	cholesterol management.			
The Norwegian Multicenter Study Group. 1981.	This study evaluated mortality and reinfarction for suspected acute MI patients who were treated with the beta-blocker timolol.	Randomized	A reduction in both reinfarction and mortality was found in patients surviving an acute MI when timolol treatment was started seven to 28 days after the onset of symptoms and continued for up to 33 months.	Patients with contraindications, such as uncontrolled cardiac failure, resting heart rate of less than 50 beats per minute, and second or third degree AV block were excluded from this study.
Quality Care Alert	This article says that beta-blockers are underutilized even though they have been proven to decrease mortality.	Not applicable	The benefits of beta-blockers for individuals with certain relative contraindications may outweigh the disadvantages. These relative contraindications include: asthma, diabetes mellitus, chronic obstructive pulmonary disease, severe peripheral vascular disease, PR interval greater than 0.24 second, and moderate or severe LV failure.	Patients who have a high chance of reinfarction, which includes individuals with a history of infarction, benefit from beta-blockers if they do not have contraindications to that therapy.
Radford, MJ, Krumholz, HM. 1998.	Not applicable	Editorial	Beta-blockers have been found to be beneficial for certain patients. However, we lack information for patients with contraindications, who are often elderly. It is critical that the results demonstrated in beta-blocker trials are applied to appropriate patient population.	None
Rasmussen, K. 1981.	This is a review of information regarding pacing indications in sinus node disease.	Review	Pacemaker implantation should, in general, be restricted to symptomatic bradycardia patients.	This article briefly mentions that some patients treated with medications may need pacing treatment in order to continue taking the drugs.
Rubenstein, J. 1972.	The purpose of this article is to describe the clinical spectrum of a group of patients with sick sinus syndrome.	Case series	Pacing was successful in treating symptoms due to bradycardia, but was less successful in preventing tachyarrhythmias.	There is no therapy indicated for patients with asymptomatic bradycardia. There were no cases of patients with second or third degree AV block.
Soumerai, Stephen B, et al.	This study seeks to discover the adverse	Cohort	Only 21% of eligible patients received beta-	The primary study population included

1997.	outcomes of beta-blocker under utilization in the post MI elderly population.		blocker therapy; this rate remained unchanged from 1987 to 1991. Controlling for other predicators of survival, the mortality rate among beta-blocker recipients was 43% less than that for non-recipients. Beta-blockers are underused in the elderly population.	post MI patients who had no measurable absolute or relative contraindications to beta-blockers.
Spargias, KS, et al. 1998.	ACE-inhibitors have been demonstrated to improve survival for patients post MI. This article analyzed the clinical outcomes and tolerance problems associated with ACE-inhibition with respect to age in a post MI population.	Randomized	A 36% mortality risk reduction was demonstrated for elderly patients with heart failure, post MI, who are treated with ace inhibitors.	Note: we only reviewed the abstract.
Squire, Ian B, et al. 2000.	For patients with heart failure, ACE-inhibitors and beta-blockers have been demonstrated to be a beneficial treatment.	Review	The available data concerning beta-blockers reflects symptomatic patients with mild to moderate heart failure. ACE-inhibitors may provide greater benefit when combined with beta- blockers.	Patients included in these trials may not adequately reflect patients in the elderly population.
Tuman, Kenneth, McCarthy, Robert. 1999.	Not applicable	Editorial	Clinicians select clinical variables as a guide to beta-blocker dosing. One variable typically used is heart rate.	None