

The background of the slide is a grayscale ECG (heart rate) strip. The text is overlaid on this background. The ECG shows several leads: I, aVR, V1, V4, II, aVL, V2, V5, III, aVF, V3, V6. The text is centered and reads:

**PREVENTION OF POST-OP
ATRIAL FIBRILLATION (POAF)**

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**Disclosures: funding for research from Wyeth-Ayerst
funding for research from Medtronic Inc**

This presentation will provide a general overview of the advantages, disadvantages, and risks of the dominant treatment strategies used to prevent atrial fibrillation after cardiac surgery.

Relative to this presentation, Dr. Mitchell discloses having received research funding from Wyeth-Ayerst Pharmaceuticals and from Medtronic Inc.

PREVENTION OF POST-OP AF

Why Should We Bother?

1. Is POAF a frequent problem?
2. Does POAF have important consequences?
3. Can POAF be prevented?
4. Can POAF be prevented safely?
5. Does prevention mitigate the consequences?

The decision to provide therapy for the purpose of prevention of post-operative atrial fibrillation after cardiac surgery will consider the probable incidence of post-operative atrial fibrillation, the potential consequences of post-operative atrial fibrillation, the likelihood that prophylactic therapy will prevent post-operative atrial fibrillation, the safety of the therapy provided to prevent post-operative atrial fibrillation, and the potential advantages of preventing post-operative atrial fibrillation relative to its consequences.

PREVENTION OF POST-OP AF

Definition of Terms

incidence = probability of first occurrence in a given time period

relative risk (RR) = incidence with Rx / incidence in control

relative risk reduction (RRR) = 1.0 – relative risk

absolute risk reduction (ARR) = incidence in control - incidence with Rx

number needed to treat (NNT) = 1 / absolute risk reduction

95% confidence interval (95% CI) = measure of reliability of estimate

This presentation will use the statistical terms defined here. Incidence is defined as the probability of first occurrence of an event in a given time period (usually expressed as either a percentage or as its corresponding decimal). Relative risk (RR) is defined as the incidence of an event in the treated group divided by the incidence in the control group (usually expressed as either a percentage or as its corresponding decimal: RR smaller than 1.0 indicate a benefit of therapy, RR greater than 1.0 indicate harm from therapy). Relative risk reduction (RRR) is defined as 100% minus the relative risk expressed as a percentage or 1.0 minus the relative risk expressed as a decimal. Absolute risk reduction (ARR) is defined as the incidence in the control group minus the incidence in the treated group (usually expressed as either a percentage or as its corresponding decimal). The number needed to treat (NNT) is defined as the number of patients that must be treated to prevent one endpoint and is calculated as 100% divided by the absolute risk reduction expressed as a percentage or 1.0 divided by the absolute risk reduction expressed as a decimal. The 95% confidence interval (95% CI) provides a measure of the reliability of a point estimate of any of the parameters defined above and indicates the range of values that would contain 95% of the point estimates for that parameter that would be expected to result from repeated experiments designed to measure that parameter's specific value.

PREVENTION OF POST-OP AF

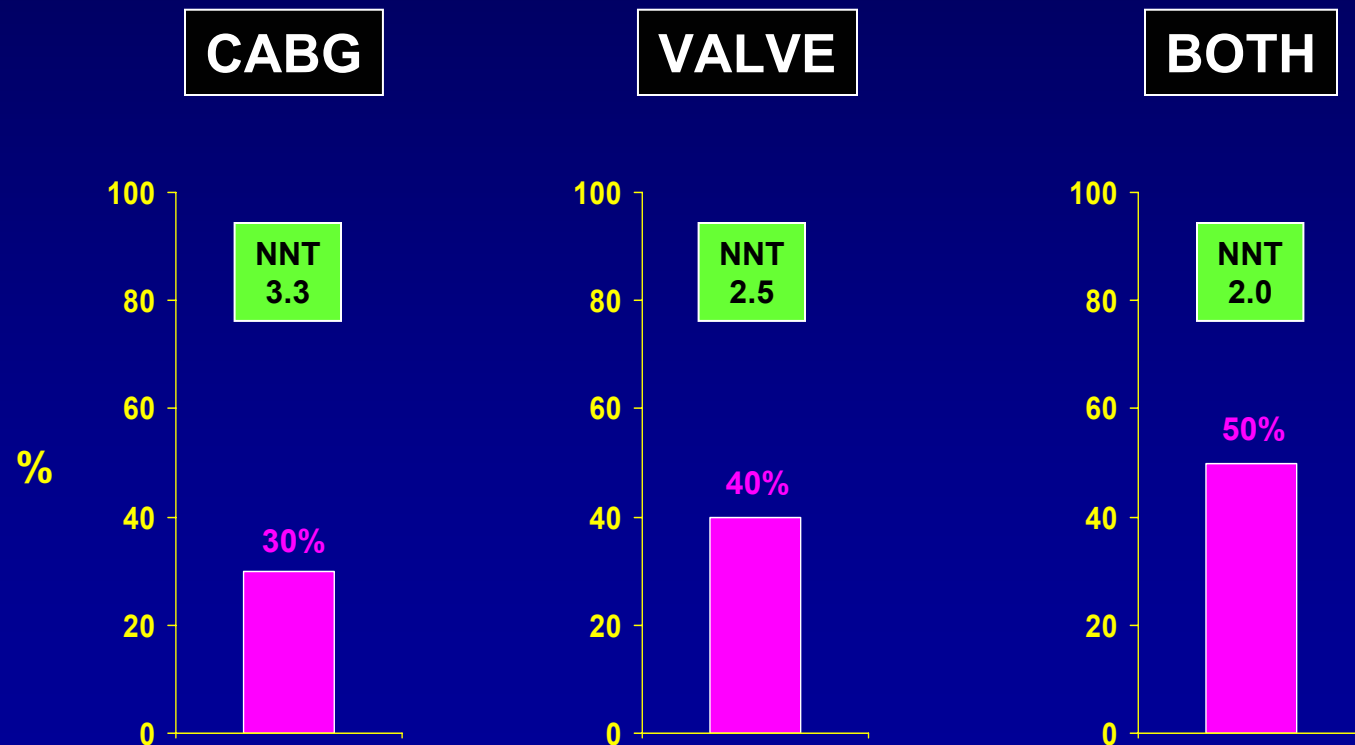
Why Should We Bother?

1. Is POAF a frequent problem?
2. Does POAF have important consequences?
3. Can POAF be prevented?
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Now to return to the questions relevant to a decision to provide therapy for the prevention of post-operative atrial fibrillation after cardiac surgery. Firstly, is post-operative atrial fibrillation a frequent problem?

PREVENTION OF POST-OP AF

Incidence of POAF - the 30/40/50 Rule



Mitchell LB in Steinberg J ed. Atrial Fibrillation after Cardiac Surgery pp37 50, 2000

These data estimate the expected incidence of post-operative atrial fibrillation after cardiac surgery based upon the operation performed by combining the outcomes reported in the control groups of forty randomized clinical trials of prophylactic therapy with the outcomes reported in three large observational trials in the absence of prophylactic therapy. Rounding the results of this analysis to memorable numbers, the incidence of post-operative atrial fibrillation was 30% after coronary artery bypass grafting surgery (CABG), 40% after valve surgery, and 50% after combined coronary artery bypass graft surgery and valve surgery. If all post-operative atrial fibrillation could be prevented (an unlikely event), the number of patients needed to treat (NNT) to prevent one patient from having post-operative atrial fibrillation would be 3.3 (100% / 30%) for coronary artery bypass surgery, 2.5 (100% / 40%) for valve surgery, and 2.0 (100% / 50%) for combined coronary artery bypass surgery and valve surgery.

PREVENTION OF POST-OP AF

Why Should We Bother?

1. Is POAF a frequent problem?
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Having concluded that post-operative atrial fibrillation after cardiac surgery is common (indeed, the most common post-operative complication), the second question relevant to a decision to provide therapy for the prevention of post-operative atrial fibrillation after cardiac surgery considers the potential consequences of this complication.

PREVENTION OF POST-OP AF

Potential Consequences of POAF

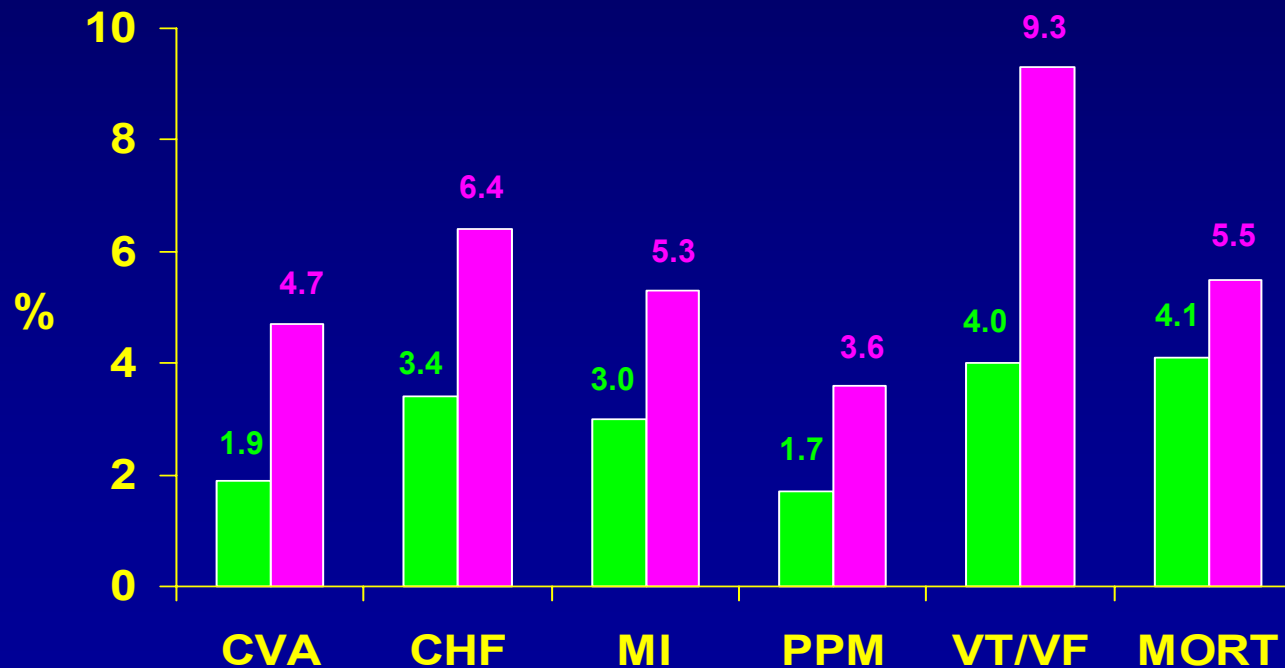
- none
- palpitations / anxiety
- hemodynamic deterioration
- neurologic events (TIA/CVA)
- exposure to risks of AA drug therapy
- exposure to risks of anticoagulant therapy
- prolongation of hospital stay
- increased hospital costs
- death

For most patients who experience post-operative atrial fibrillation after cardiac surgery, the rhythm disturbance does not have significant consequences. Nevertheless, many patients will experience symptoms (particularly those of palpitations and/or anxiety) and a few will develop hemodynamic deterioration. The post-operative occurrence of atrial fibrillation has also been associated with neurologic events such as transient ischemic attack (TIA) or stroke (CVA), with exposure to the risks of antiarrhythmic (AA) drug therapy, with exposure to the risks of anticoagulant therapy, with prolongation of hospital stay, with increased hospital costs, and with death.

PREVENTION OF POST-OP AF

Potential Consequences of POAF

patients **without POAF** versus patients **with POAF**



The magnitude of the associations between adverse patient outcomes and post-operative atrial fibrillation after cardiac surgery are shown on this slide derived from the combined results of three large observational trials of cardiac surgery patients. From a total sample of 10,673 patients, significantly more patients with post-operative atrial fibrillation had a CVA than did patients without post-operative atrial fibrillation (4.7% versus 1.9%, relative risk 2.5, 95% CI for relative risk 2.0 – 3.2). From a total sample of 6,690 patients, significantly more patients with post-operative atrial fibrillation had progressive congestive heart failure than did patients without post-operative atrial fibrillation (6.4% versus 3.4%, relative risk 1.9, 95% CI for relative risk 1.5 – 2.4). From a total sample of 4,425 patients, significantly more patients with post-operative atrial fibrillation had a peri-operative myocardial infarction than did patients without post-operative atrial fibrillation (5.3% versus 3.0%, relative risk 1.8, 95% CI for relative risk 1.3 – 2.4). From a total sample of 4,553 patients, significantly more patients with post-operative atrial fibrillation required permanent pacemaker implantation than did patients without post-operative atrial fibrillation (3.6% versus 1.7%, relative risk 2.2, 95% CI for relative risk 1.5 – 3.2) and significantly more patients with post-operative atrial fibrillation experienced VT/VF than did patients without post-operative atrial fibrillation (9.3% versus 4.0%, relative risk 2.4, 95% CI for relative risk 1.8 – 3.0). Finally, from a total sample of 8,408 patients, significantly more patients with post-operative atrial fibrillation died than did patients without post-operative atrial fibrillation (5.2% versus 4.1%, relative risk 1.3, 95% CI for relative risk 1.0 – 1.6).

PREVENTION OF POST-OP AF

Why Should We Bother?

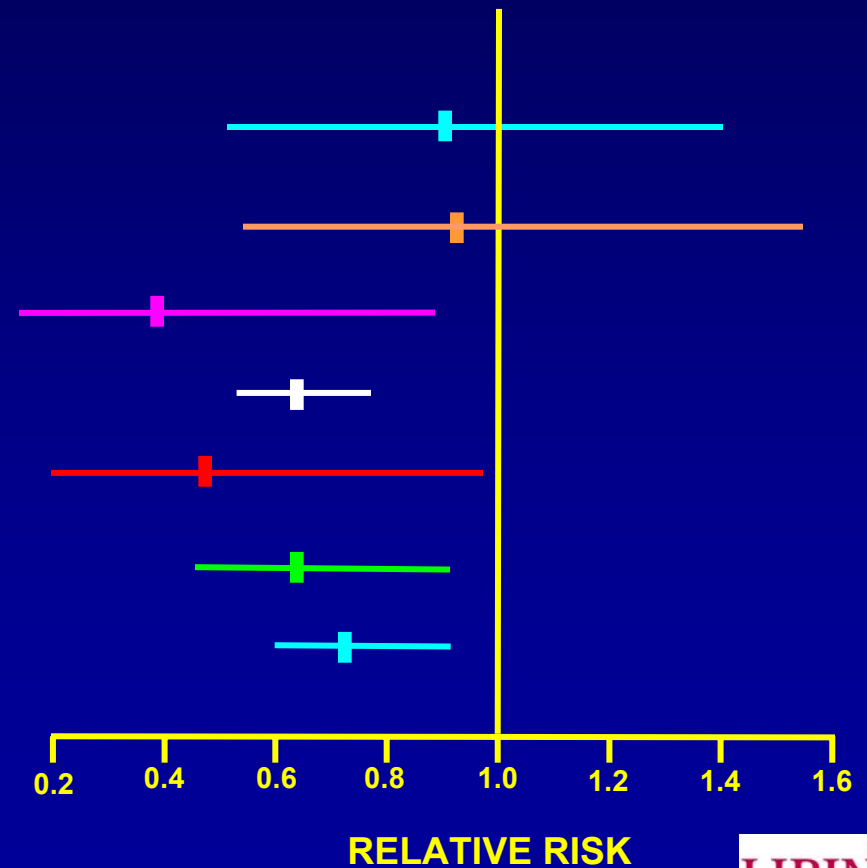
1. Is POAF a frequent problem?
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Having concluded that post-operative atrial fibrillation after cardiac surgery is common and can have serious consequences, the third question relevant to a decision to provide therapy for the prevention of post-operative atrial fibrillation after cardiac surgery considers whether or not post-operative atrial fibrillation can be prevented.

PREVENTION OF POST-OP AF

Therapies With No or Weak Evidence of Efficacy

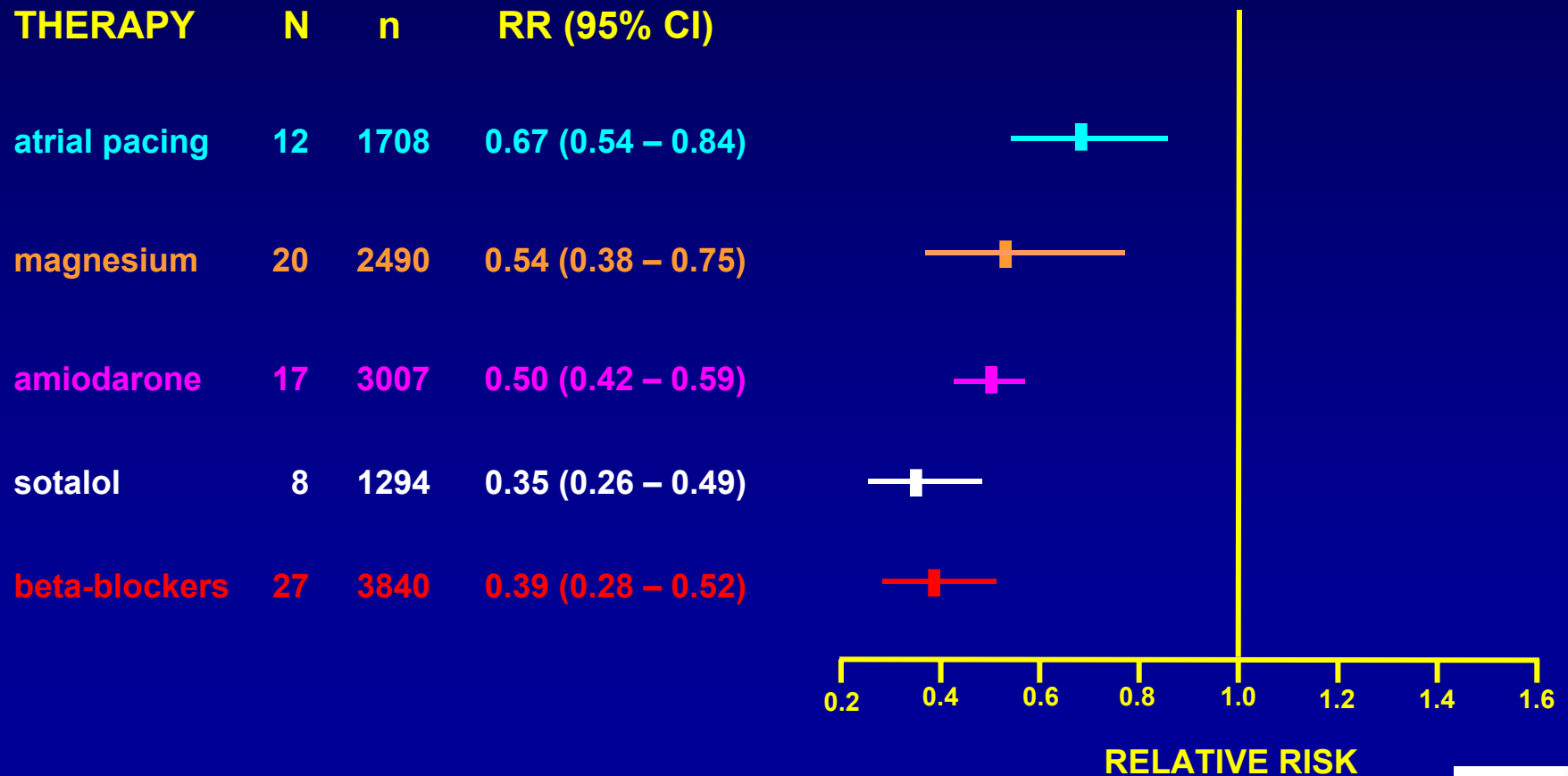
THERAPY	N	n	RR (95% CI)
digoxin	7	709	0.91 (0.51 – 1.40)
verapamil	3	432	0.94 (0.56 – 1.58)
naprosen	1	98	0.38 (0.16 – 0.92)
diltiazem	5	639	0.64 (0.53 – 0.76)
procainamide*	2	146	0.47 (0.22 – 0.99)
propafenone*	1	293	0.62 (0.43 – 0.91)
corticosteroids*	3	596	0.71 (0.60 – 0.85)



A very large number of therapies have been evaluated for efficacy for the prevention of post-operative atrial fibrillation after cardiac surgery. Shown here are estimates of the efficacies of therapies that have either been extensively studied without evidence of benefit or that have shown a suggestion of benefit but have only been studied in small patient populations. For each therapy, the number of trials evaluating that therapy (N) and the total number of patients involved in trials of that therapy (n) are shown along with the estimate of relative risk (RR) and the 95% confidence interval (95% CI) around that point estimate of relative risk. The RR and 95% CI are also shown graphically on the right side. For each of these therapies, the point estimate of RR falls on the left side of the 1.0 RR line (suggesting benefit). When the 95% confidence interval for RR crosses the 1.0 RR line, the suggestion of benefit is not statistically-significant (digoxin, verapamil). When the right portion of the 95% CI range falls to the left of the 1.0 RR line, the suggestion of benefit is statistically-significant (naprosen, diltiazem, procainamide, propafenone, corticosteroids). * Of course, concern has been expressed with respect to the potential proarrhythmic effects of procainamide and propafenone in patients who, by definition, have structural heart disease and with respect to the potential adverse effects of corticosteroids on healing after surgery.

PREVENTION OF POST-OP AF

Therapies With Better Evidence of Efficacy

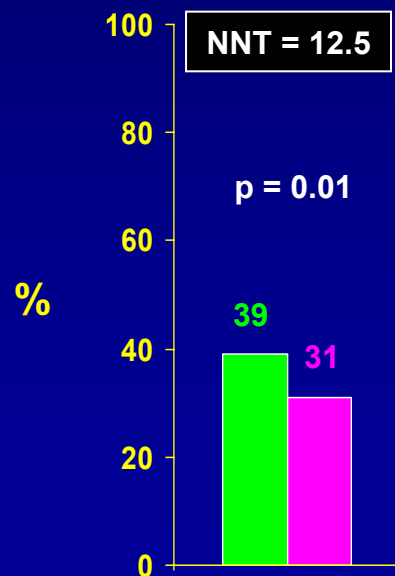


Shown here are estimates of the efficacy of therapies that have been extensively studied and have shown a statistically-significant benefit for the purpose of prevention of post-operative atrial fibrillation after cardiac surgery. For each therapy, the number of trials evaluating that therapy (N) and the total number of patients involved in trials of that therapy (n) are shown along with the estimate of relative risk (RR) and the 95% confidence interval (95% CI) around that point estimate of relative risk. The RR and 95% CI are also shown graphically on the right side. For each of these therapies, the point estimate of RR falls on the left side of the 1.0 RR line (suggesting benefit) and the 95% confidence interval range for RR does not cross the 1.0 RR line (indicating statistical significance). Of these therapies, the evidence of benefit is strongest for amiodarone, sotalol, and the standard beta-blocker drugs – hereinafter referred to as the big three.

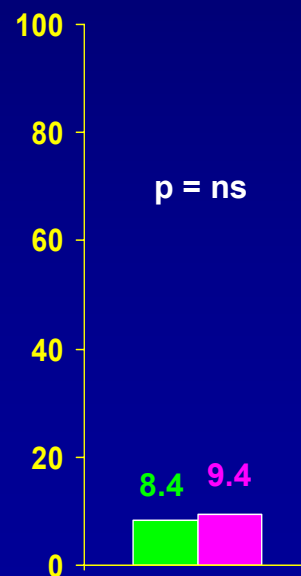
Beta-blocker Length Of Stay (BLOS) Study

- 1000 heart surgery pts (62 yrs, 79% male, 85% CABG alone)
- randomized to **placebo** versus **metoprolol** (100/150 mg / day)
- primary outcome = post-operative length of stay

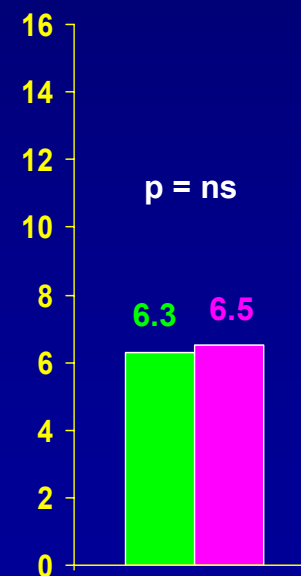
POAF (%)



AE (%)



LOS (days)

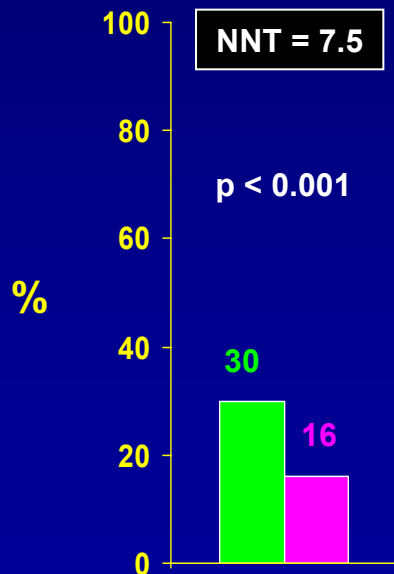


The largest and most contemporary of the trials of standard beta-blocker drugs for the prevention of post-operative atrial fibrillation after cardiac surgery was the Beta-blocker Length of Stay (BLOS) study. One thousand patients having cardiac surgery were randomly assigned to receive placebo treatment or to receive 100 mg of metoprolol per day (increased to 150 mg per day later in the trial) starting immediately after surgery. The incidence of post-operative atrial fibrillation was statistically-significantly ($p = 0.01$) lower in metoprolol-treated patients than in placebo-treated patients (31% versus 39%) (RR 0.80; 95% CI for RR 0.74 – 0.96; NNT 12.5). However, there were no statistically-significant differences between the two study populations with respect to post-operative adverse events (AE) or with respect to length of post-operative hospital stay (LOS).

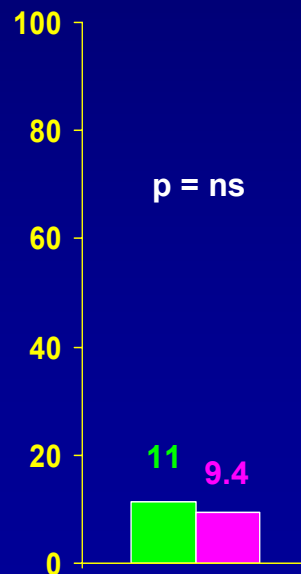
The PAPABEAR Study

- 601 heart surgery pts (62 yrs, 82% male, 65% CABG alone)
- randomized to **placebo** versus **amiodarone** (10 mg / kg / day)
- primary outcome = POAF

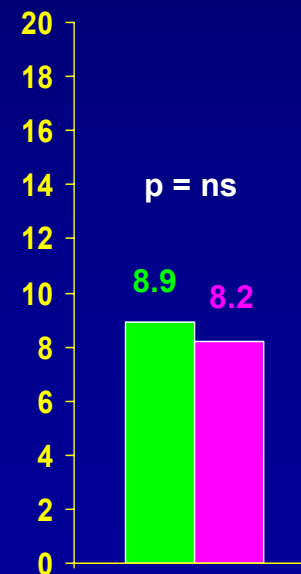
POAF (%)



COMP(%)



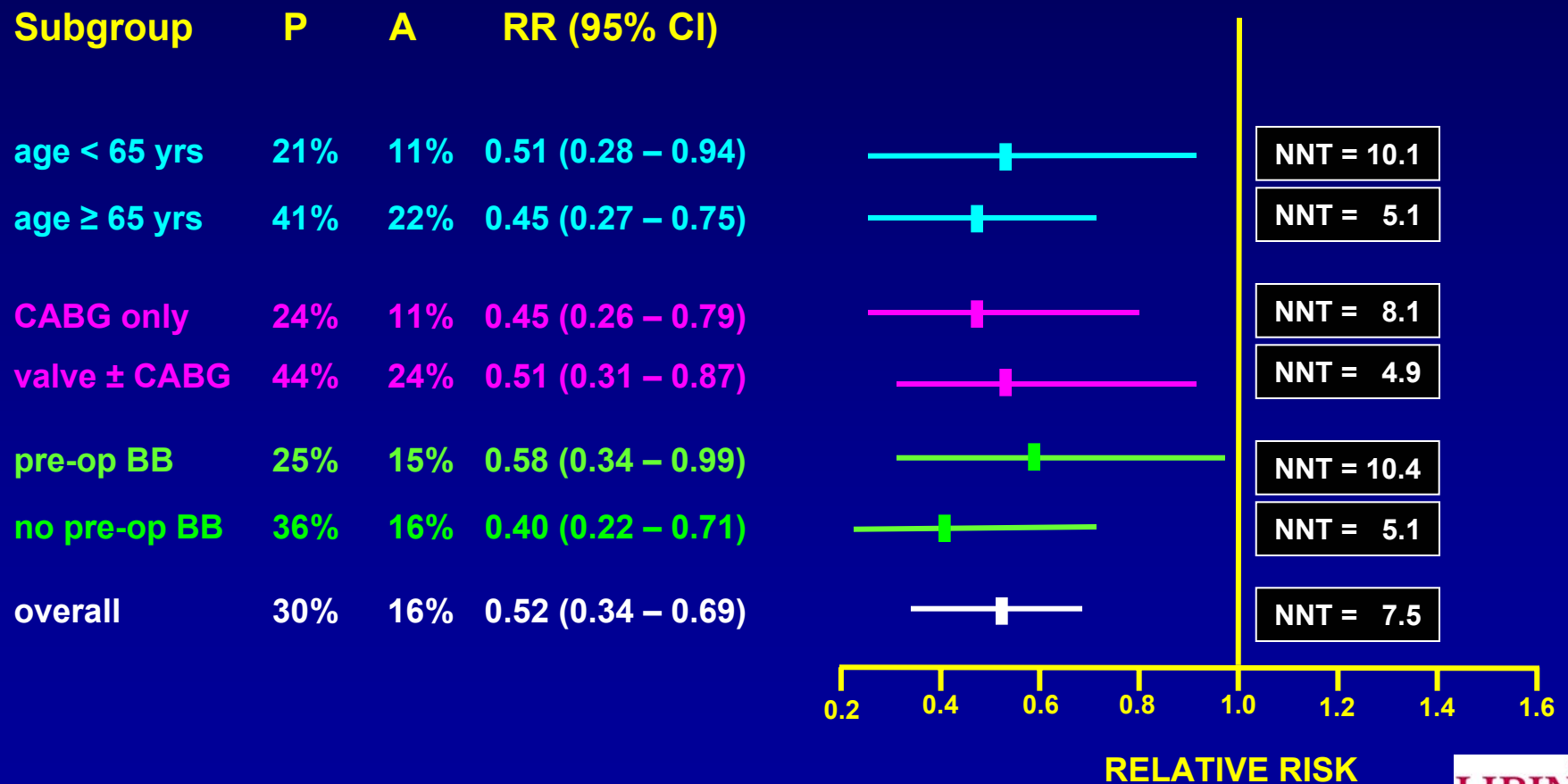
LOS (days)



The largest and most contemporary of the trials of amiodarone for the prevention of post-operative atrial fibrillation after cardiac surgery was the Prophylactic Amiodarone for the Prevention of Arrhythmias that Begin Early After Revascularization, valve replacement or repair (PAPABEAR) study. Six hundred and one patients having cardiac surgery were randomly assigned to receive placebo treatment or to receive 10 mg / kg / day of amiodarone starting 7 days prior to surgery. The incidence of post-operative atrial fibrillation was statistically-significantly ($p = 0.001$) lower in amiodarone-treated patients than in placebo-treated patients (30% versus 16%) (RR 0.52; 95% CI for RR 0.34 – 0.69; NNT 7.5). However, there were no statistically-significant differences between the two study populations with respect to post-operative complications (COMP) or with respect to length of post-operative hospital stay (LOS).

The PAPABEAR Study

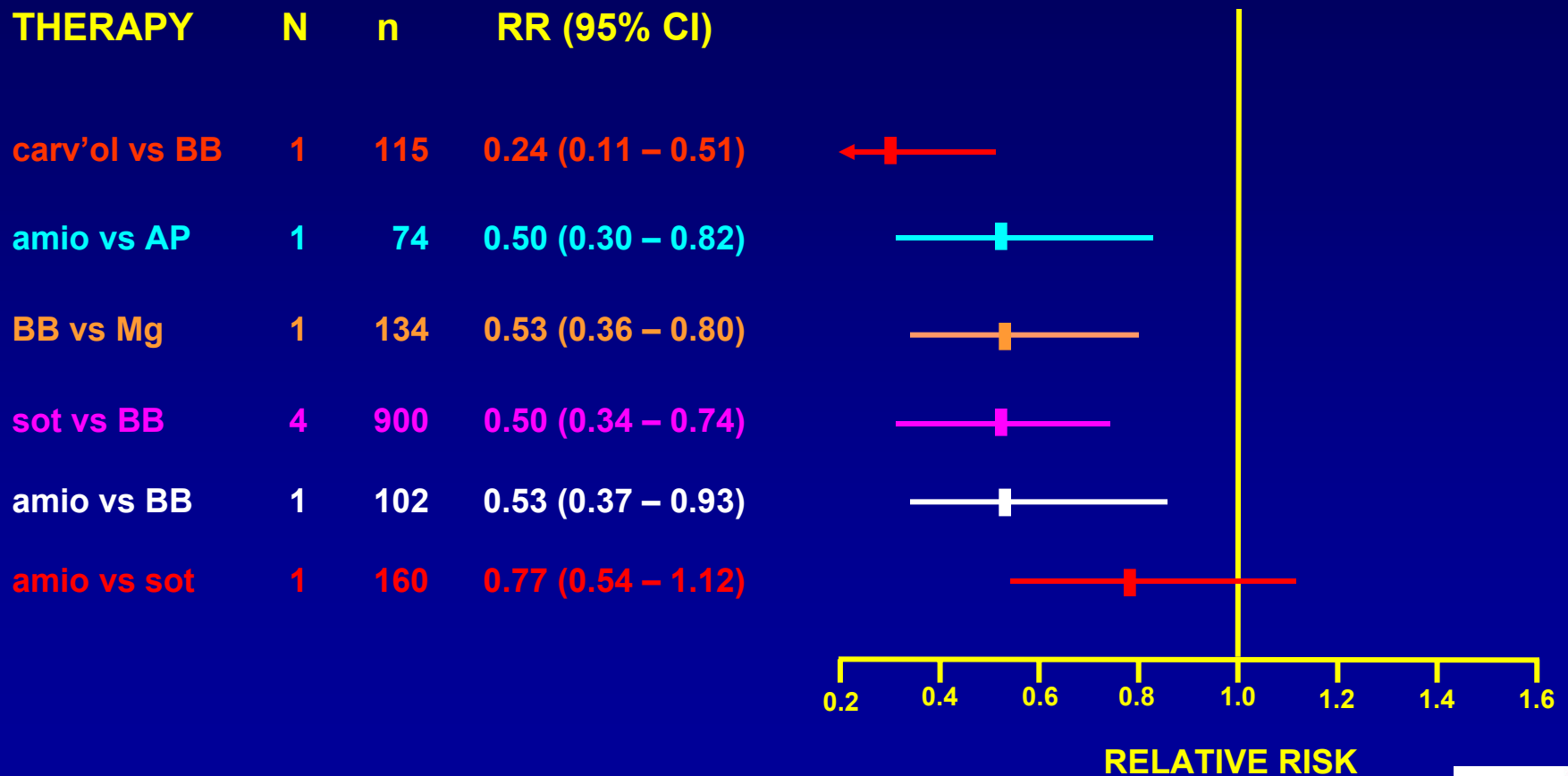
Stratified Subgroup Analysis for POAF



Randomization in the Prophylactic Amiodarone for the Prevention of Arrhythmias that Begin Early After Revascularization, valve replacement or repair (PAPABEAR) study was stratified for age (< 65 years versus \geq 65 years), operation performed (CABG only versus valve surgery with or without concomitant CABG), and use of pre-operative beta-blocker drug therapy (yes versus no). Thus, each of these subgroups can be analyzed separately without subverting the randomization process. The incidence of post-operative atrial fibrillation was higher in patients ages 65 years or greater, in patients who had valve surgery, and in patients not receiving pre-operative beta-blocker drug therapy. The relative risks (RR) associated with amiodarone therapy are comparable in each of the six pre-specified subgroups. Subgroups with higher probabilities of post-operative atrial fibrillation had larger absolute risk reductions that translate into lower numbers needed to treat (NNT) to prevent one patient from experiencing post-operative atrial fibrillation. Thus, amiodarone therapy is effective for the prevention of post-operative atrial fibrillation regardless of age, surgery performed, or presence or absence of concomitant beta-blocker drug therapy. $P = \text{incidence in placebo-treated patients}$, $A = \text{incidence in amiodarone treated patients}$.

PREVENTION OF POST-OP AF

Comparisons of Therapies With Efficacy



The various prophylactic therapies for the prevention of post-operative atrial fibrillation after cardiac surgery have been compared in a few randomized trials. In one trial of 115 patients, carvedilol (carv'ol) was reported to have superior efficacy to other standard beta-blocker (BB) drugs (predominantly metoprolol or atenolol); in one trial of 74 patients, amiodarone (amio) therapy was reported to have superior efficacy to fixed high-rate atrial septal pacing (AP); in one trial of 134 patients, standard beta-blocker (propranolol) therapy was reported to have superior efficacy to IV magnesium (Mg); in four trials involving 900 patients, sotalol (sot) therapy was reported to have superior efficacy to standard beta-blocker drug therapy; in one trial of 102 patients, amiodarone therapy was reported to have superior efficacy to standard beta-blocker drug (propranolol) therapy; and, in one trial of 160 patients amiodarone therapy was reported to have superior efficacy to sotalol therapy (although the latter difference was not statistically-significant). These data weakly suggest that, in order of efficacy, the big three therapies could be ranked amiodarone/sotalol, standard beta-blocker drugs.

PREVENTION OF POST-OP AF

Why Should We Bother?

1. Is POAF a frequent problem?
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3. Can POAF be prevented?
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Having concluded that post-operative atrial fibrillation after cardiac surgery is common, can have serious consequences, and can be prevented, the fourth question relevant to a decision to provide therapy for the prevention of post-operative atrial fibrillation after cardiac surgery considers whether or not post-operative atrial fibrillation can be prevented safely.

PREVENTION OF POST-OP AF

Therapy-Related Adverse Events – The Big Three

standard beta-blockers

- evidence¹ for bradycardia (5-10%)
- evidence² for longer ventilation (1-2%)

sotalol

- evidence³ for bradycardia (10-15%)
- evidence⁴ for torsade de pointes VT (1-5%)

amiodarone

- evidence⁵ for bradycardia (2-5%)
- evidence⁵ for hypotension with IV (2-5%)
- evidence⁶ for QT prolongation (1-2%) (but not VT)

1. Am Heart J 147:636 4, 2004

2. Am Heart J 145:226 3, 2003

3. Chest 121:1203 10, 2002

4. Drug Saf 25:847 65, 2002

5. Am J Health Syst Pharm 63:829 3, 2006

6. JAMA 294:3093 10, 2005

The vast majority of the placebo-controlled, randomized clinical trials of prophylactic therapy for the prevention of post-operative atrial fibrillation after cardiac surgery were not powered to assess potential therapy-related adverse events that occur with low frequencies. Accordingly, the data presented on this slide are derived from the larger randomized trials of prophylactic therapy (1,2,6), from meta-analyses (3,5), or from reports of drug use in other settings (4). These data weakly suggest that in order of safety, the big three therapies could be ranked beta-blocker drugs, amiodarone/sotalol.

PREVENTION OF POST-OP AF

Why Should We Bother?

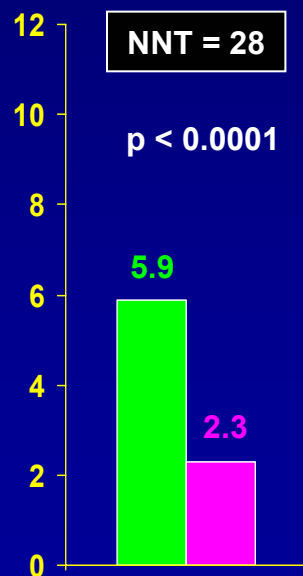
1. Is POAF a frequent problem?
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Having concluded that post-operative atrial fibrillation after cardiac surgery is common, can have serious consequences, can be prevented, and can be prevented relatively safely, the fifth question relevant to a decision to provide therapy for the prevention of post-operative atrial fibrillation after cardiac surgery considers whether or not the prevention post-operative atrial fibrillation can prevent the adverse patient outcomes associated with post-operative atrial fibrillation.

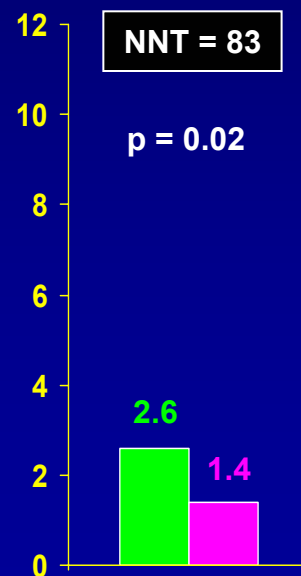
The Bagshaw Amiodarone Meta-Analysis

- 19 randomized, amiodarone trials for prevention of POAF
- placebo (N = 1656) versus amiodarone (N = 1639)
- total 3295 patients

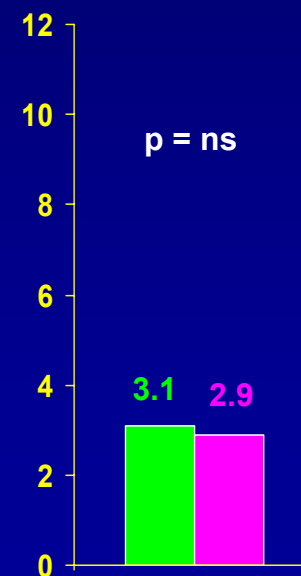
VT/VF (%)



NEURO(%)



MORT (%)

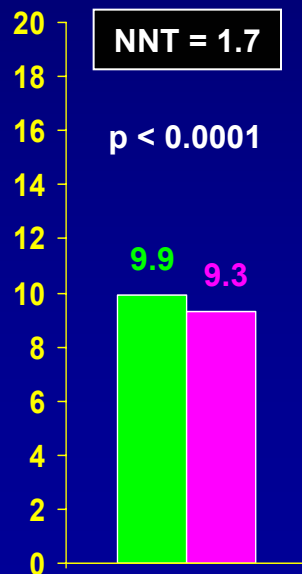


As we have seen earlier, the incidences of the adverse patient outcomes associated with atrial fibrillation are very low. No single study performed to date has been powered to detect treatment-related differences in the incidences of these adverse patient outcomes. Accordingly, demonstration that the prevention of post-operative atrial fibrillation after cardiac surgery results in a reduced incidence of the adverse patient outcomes associated with atrial fibrillation has been difficult. The best evidence that this goal can be achieved is to be found in the meta-analysis of randomized trials of amiodarone prophylaxis performed by Bagshaw et al. Nineteen trials involving 3295 patients were pooled. The incidence of post-operative atrial fibrillation was reduced with amiodarone (RR 0.50, 95% CI for RR 0.43 – 0.59, $p < 0.0001$). In association with the reduction in post-operative atrial fibrillation, the pooled analysis found a reduction in the incidence of post-operative VT/VF from 5.9% to 2.3% (RR 0.39, 95% CI for RR 0.26 – 0.58, $P < 0.0001$) translating into a number needed to treat (NNT) of 28 to prevent one patient from experiencing VT/VF. Amiodarone treatment also reduced the incidence of neurologic events (transient ischemic attack or stroke) from 2.6% to 1.4% (RR 0.53, 95% CI for RR 0.30 – 0.92) translating into a number needed to treat (NNT) of 83 to prevent one patient from experiencing an adverse neurologic event. Although the surgical mortality rate was also lower in amiodarone-treated patients, this difference was not statistically-significant.

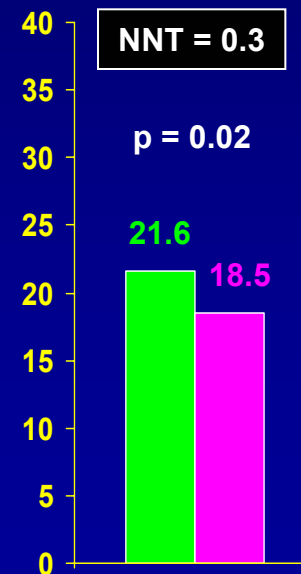
The Bagshaw Amiodarone Meta-Analysis

- 19 randomized, amiodarone trials for prevention of POAF
- placebo (N = 1656) versus amiodarone (N = 1639)
- total 3295 patients

LOS (days)



COST (\$K)



The Bagshaw meta-analysis of randomized amiodarone trials for the purpose of prevention of post-operative atrial fibrillation after cardiac surgery also showed that amiodarone therapy was associated with a shorter post-surgical hospital length of stay (LOS) (9.3 versus 9.9 days, $p < 0.0001$) translating into a number needed to treat (NNT) of 1.7 to save one hospital day. Amiodarone therapy also reduced the costs associated with cardiac surgery (\$21,737 to \$18,548, $p = 0.02$) translating into a number needed to treat (NNT) of 0.3 to save \$1000 in hospital costs.

PREVENTION OF POST-OP AF

Why Should We Bother?

- 1. Is POAF a frequent problem?**
- 2. Does POAF have important consequences?**
- 3. Can POAF be prevented?**
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To return to our original questions central to the decision to prescribe prophylactic therapy for the purpose of preventing post-operative atrial fibrillation after cardiac surgery...

PREVENTION OF POST-OP AF

Why Should We Bother?

1. Is POAF a frequent problem?
 - see 30%, 40%, 50% rule
2. Does POAF have important consequences?
3. Can POAF be prevented?
4. Can POAF be prevented safely?
5. Does prevention mitigate the consequences?

Post-operative atrial fibrillation after cardiac surgery is frequent with an incidence of approximately 30% after isolated coronary artery bypass surgery, approximately 40% after isolated valve surgery, and approximately 50% after combined coronary artery bypass surgery and valve surgery.

PREVENTION OF POST-OP AF

Why Should We Bother?

1. Is POAF a frequent problem?
 - see 30%, 40%, 50% rule
2. Does POAF have important consequences?
 - TIA/CVA, CHF, MI, PPM, VT/VF, mort
3. Can POAF be prevented?
4. Can POAF be prevented safely?
5. Does prevention mitigate the consequences?

The occurrence of post-operative atrial fibrillation after cardiac surgery is associated with adverse patient outcomes including adverse neurological events (TIA/CVA), worsening congestive heart failure (CHF), myocardial infarction (MI), need for permanent pacing (PPM), ventricular tachyarrhythmias (VT/VF), and increased operative mortality (mort)..

PREVENTION OF POST-OP AF

Why Should We Bother?

1. Is POAF a frequent problem?
 - see 30%, 40%, 50% rule
2. Does POAF have important consequences?
 - TIA/CVA, CHF, MI, PPM, VT/VF, mort
3. Can POAF be prevented?
 - yes – amio, sotalol, beta-blocker
4. Can POAF be prevented safely?
5. Does prevention mitigate the consequences?

Post-operative atrial fibrillation after cardiac surgery can be prevented. The treatments with the best evidence for efficacy in approximate order of their efficacy are amiodarone/sotalolol and standard beta-blocker drugs.

PREVENTION OF POST-OP AF

Why Should We Bother?

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 - see 30%, 40%, 50% rule
2. Does POAF have important consequences?
 - TIA/CVA, CHF, MI, PPM, VT/VF, mort
3. Can POAF be prevented?
 - yes – amio, sotalol, beta-blocker
4. Can POAF be prevented safely?
 - yes – beta-blocker, amio, sotalol
5. Does prevention mitigate the consequences?

Post-operative atrial fibrillation after cardiac surgery can be prevented safely. The treatments with the best evidence for safety in this setting in approximate order of their efficacy are standard beta-blocker drugs and amiodarone/sotalolol.

PREVENTION OF POST-OP AF

Why Should We Bother?

1. Is POAF a frequent problem?
 - see 30%, 40%, 50% rule
2. Does POAF have important consequences?
 - TIA/CVA, CHF, MI, PPM, VT/VF, mort
3. Can POAF be prevented?
 - yes – amio, sotalol, beta-blocker
4. Can POAF be prevented safely?
 - yes – beta-blocker, amio, sotalol
5. Does prevention mitigate the consequences?
 - yes – reduced VT/VF, TIA/CVA, LOS

The prevention of post-operative atrial fibrillation after cardiac surgery is associated with a reduction in the incidence of associated adverse patient outcomes. The evidence in support of this statement is strongest for amiodarone therapy with respect to reducing the incidence of post-operative ventricular tachyarrhythmias (VT/VF), adverse neurological events (TIA/CVA), and the length of hospital stay (LOS).

The background of the slide is a grayscale ECG (heart rate) strip. The text is overlaid on the grid. The ECG shows a regular rhythm with a rate of approximately 75 bpm. The leads are labeled I, aVR, V1, V4, II, aVL, V2, V5, III, aVF, V3, V6. The text is centered and reads:

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funding for research from Medtronic Inc**

From these data, I conclude that the prevention of post-operative atrial fibrillation after cardiac surgery is a worthwhile goal. At the very least (in patients already receiving beta-blocker drug therapy), withdrawal of the beta-blocker drug therapy should be avoided. As an intermediate approach (for patients at lower risk of atrial fibrillation), evidence for a favorable balance of safety and efficacy is strongest for the standard beta-blocker drugs. As a more assertive approach (for patients at higher risk of atrial fibrillation), prophylactic amiodarone therapy has the apparent advantage of greater efficacy.