

Best Medical Treatment (BMT) Subcommittee

A: Aims:

- Recommendation of best medical treatment for patients enrolled into CABACS
- Definition of risk factors
- Recommendations for life style modifications
- Recommendations for antiplatelet therapy
- Recommendations for treatment aims

B: Patient population:

All patients enrolled into CABACS will be treated by best medical treatment, irrespective of whether they are randomized into the group isolated CABG or simultaneous CABG plus CEA.

C.: Definitions and references for measurement

Obesity:

Obesity as a risk factor is stratified according to the body-mass-index (BMI). BMI is the ratio of weight and the square of the body height (kilogram/metre²).

Obesity and pre-obesity are defined as BMI greater or equal 25 kilogram/metre², obesity is defined as BMI greater 30 kilogram/metre².

It is further graded into grade one (30-34.9), grade two (35-39.9) and grade three (>40).

Patients with a BMI > 25 kg/m² should have a measurement of the waist circumference. This is considered as a cardiovascular risk in women above 80 cm and men above 94 cm.

Arterial hypertension:

According to the WHO/ISH guidelines the following classification is used

Classification	systolic	diastolic
Optimal	<120	<80
Normal	<130	<85
Borderline normal	130-139	85-90
Mild hypertension (grade 1)	140-159	90-99
Moderate hypertension (grade 2)	160-179	100-109
Severe hypertension (grade 3)	≥180	≥110
Isolated systolic hypertension	≥140	>90

Measurements are performed at mid-sternal level. If sequential measurements in both arms show a blood pressure difference, further measurements are performed in the arm with the higher arterial blood pressure. Differences of greater than 20/10 mm Hg warrant further angiologic diagnostic.

Blood pressure should be measured in a sitting position paying attention to the following arm positions:

- Measurement after 5 minute rest in a quiet room

- On first measurement the systolic blood pressure should be identified by palpating the radial pressure and inflating the cuff 30 mm above this pressure to exclude an auscultation gap.
- Standard cuffs with the width of 12-13x24 cm should be used, in patients with proximal arm circumference >32 cm wider cuffs should be used.
- Systolic blood pressure equals the cuff pressure on auscultation of phase I, diastolic blood pressure is considered to be the disappearance of the Korotkoff sound (phase V). Blood pressure should be measured in decrements of 2 mm Hg and should not be rounded up or down to 5 mm Hg.
- On first examination blood pressure should be measured in both arms. Patients should be encouraged to regularly measure the blood pressure and document it.

Heart rate:

The heart rate is measured by palpating the peripheral pulse counting the beats over 30 seconds and multiplying by 2.

Impaired glucose metabolism:

The various degrees of impaired glucose metabolism are defined as follows:

Diabetes mellitus: Fasting glucose >126 mg/dl (plasma) or 2 hour level of OGTT >200 mg/dl.

Abnormal fasting glucose: Fasting glucose >100 mg/dl (plasma)

Impaired glucose tolerance: 2 hour level of measurement of OGTT >140 mg/dl (OGTT: Oral glucose tolerance testing).

D: Treatment recommendation:

1. Lifestyle modification:

Smokers should stop smoking. Pharmacologic support (nicotin chewing gum or plasters, anticraving medication with tricyclics or varenicline) can be offered as well as non pharmacological guidance.

Obesity: Patient with an obesity should reduce their weight, receive dietary counselling and diet and should be encouraged to have exercise at least 3 times a week for 30-45 minutes.

Lack of exercise: 30 minutes of physical exercise should be performed twice weekly

Alcohol: alcohol should be consumed in moderation (men <30 g/day, women <15 g/day).

2. Arterial hypertension:

Patients treated in CABACS should receive anti-hypertensive therapy if they suffer from arterial hypertension (>140/90 mm Hg, diabetics > 130/85 mm Hg).

They should receive low sodium diet (< 6 g/die), exercise and antihypertensives.

Normal blood pressure should be achieved.

For the treatment of hypertension all drug regimes can be used, they should be chosen preferentially according to the underlying medical conditions, contraindications, side-effects and compliance. The effect of primary prevention depends largely on the antihypertensive effect and not the drug used.

Drugs used should be: ACE-inhibitors, angiotensin-II-inhibitors, betablockers, calciumantagonists and diuretics. ACE-inhibitors und angiotensin-II-inhibitors should be used preferentially, often a combination of different drugs can be necessary.

3. Hyperlipidemia:

Since all patients treated in CABACS suffer from coronary heart disease or are at high risk of myocardial infarction, it should be treated with statins if they have LDL-levels of > 100 mg/dl. Simvastatin, pravastatin or atorvastatin can be used.

4. Impaired glucose tolerance: diabetics should receive diet, dietary counselling, exercise and oral antidiabetics or insulin. Normoglycemia should be achieved. HbA1c should be below 7%. According to recent clinical studies very aggressive blood-glucose lowering should be avoided. Diabetics should receive ACE-inhibitors or sartanes for the treatment of hypertension and they should receive statins.

E. Antiplatelet therapy:

All patients in CABACS should receive antiplatelet therapy. Standard therapy is ASS 100 mg/day. Gastrointestinal complaints should be treated with proton-pump-inhibitors. In cases of symptomatic peripheral arterial disease clopidogrel 75 mg/day should be given.

F.: Documentation of risk factors:

During screening and follow-up visit the following risk factors should be documented:

- Blood pressure
- Heart rate
- Weight, height, hip and waist-circumference
- Physical activity
- Smoking
- External laboratory values (glucose, HbA1c, cholesterol, LDL-cholesterol, HDL-cholesterol, triglycerides)
- medication (antiplatelet-treatment, antihypertensives, lipid-lowering agents, antidiabetics)

G: Intervention goals:

The following goals should be achieved:

Risk factor	Goal
Smoking	Cessation
Fasting cholesterol	<200 mg/die
LDL-cholesterol	<100 mg/dl
HDL-cholesterol	>40 mg/dl
Triglycerides	<150 mg/dl
Physical activity	30/45 minutes of physical activities 3-5 times/week

Obesity BMI 25-27,5 kg/m ²	Weight loss until BMI <25 kg/m ²
BMI >27,5 kg/m ²	10% weight loss
Blood pressure non- diabetics	<140/85 mm Hg
Blood pressure diabetics	< or = 130/80 mm Hg
Diabetics HbA1c	<7%

Signatures of committee members:

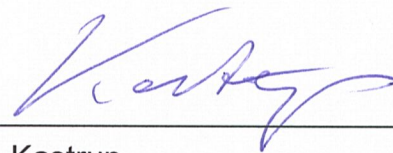
Essen 8. Juli 2010



Place, Date

Prof. Dr. H.C. Diener

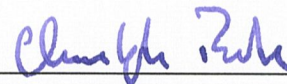
Essen 12.7.10



Place, Date

Dr. O. Kastrup

Essen, den 2.7.2010



Place, Date

Prof. Dr. Ch. Bode