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HEALTHY HEART

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Honorary Editor :

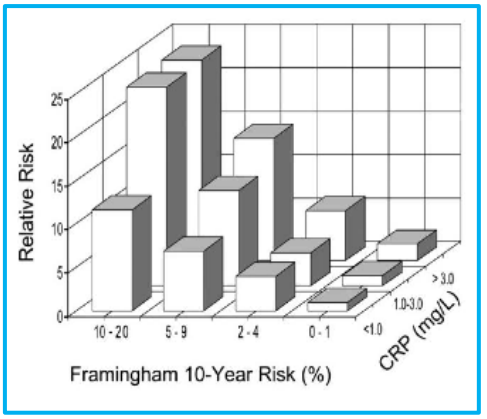
Dr. Anish Chandarana
Interventional Cardiologist

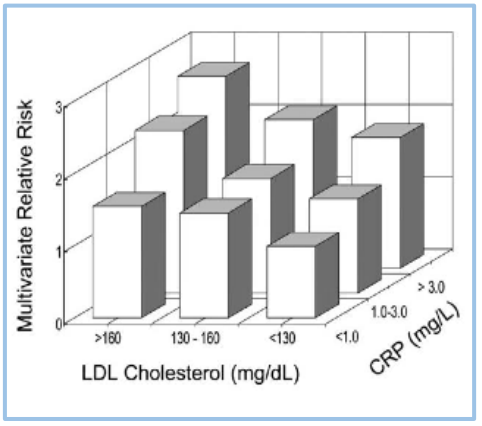
CARDIOVASCULAR INFLAMMATION: FIVE IMPORTANT THINGS A CLINICIAN MUST KNOW

Inflammatory risk is an important and relevant risk in Atherosclerotic Cardiovascular Disease (ASCVD):

ASCVD is a chronic, risk factor-driven immunoinflammatory disease, not merely a cholesterol storage disease. Risk factors like smoking, hypertension (HT), dyslipidaemia, visceral obesity, dysglycaemia etc. trigger innate and adaptive immune responses. The inflammatory response of accumulation of Apo B containing atherogenic lipoproteins leads to plaque formation, plaque progression, plaque instability and, ultimately, Acute Coronary Syndrome (ACS).

Elevated level of high sensitive C Reactive Protein (hsCRP) as a marker of cardiovascular inflammation has undergone extensive evaluation and validation. We have been predicting future ASCVD risk with the help of various clinical risk models. Ten-year Framingham risk categories can be further classified with the help of CRP levels, suggesting that presence or absence of cardiovascular inflammation has an additive value to clinical risk score. Similarly, the same levels of LDL cholesterol will predict different level of future ASCVD risk based on CRP values.





Cardiologists

Dr Tejas V. Patel	(M) +91-89403 05130
Dr Hiren Kevadiya	(M) +91-98254 65205
Dr Gunvant Patel	(M) +91-98240 61266
Dr Keyur Parikh	(M) +91-98250 26999
Dr Milan Chag	(M) +91-98240 22107
Dr Urmil Shah	(M) +91-98250 66939
Dr Hemang Baxi	(M) +91-98250 30111
Dr Anish Chandarana	(M) +91-98250 96922
Dr Ajay Naik	(M) +91-98250 82666
Dr Satya Gupta	(M) +91-99250 45780
Dr Vipul Kapoor	(M) +91-98240 99848
Dr Vineet Sankhla	(M) +91-99250 15056

Cardiothoracic & Vascular Surgeons

Dr Dhiren Shah	(M) +91-98255 75933
Dr Dhaval Naik	(M) +91-90991 11133
Dr Amit Chandan	(M) +91-96990 84097
Dr Nikunj Vyas	(M) +91-73531 65955
Dr Dhyanil Trivedi	(M) +91-99989 67576

Congenital & Structural Heart Disease Specialist

Dr Kashyap Sheth	(M) +91-99246 12288
Dr Milan Chag	(M) +91-98240 22107

Paediatric & Structural Heart Surgeon

Dr Shaunak Shah (M) +91-98250 44502

Cardiovascular, Thoracic & Thoracoscopic Surgeon

Dr Pranav Modi (M) +91-99240 84700

Cardiac Anaesthetists

Dr Niren Bhavsar	(M) +91-9879571917
Dr Hiren Dholakia	(M) +91-9586375818
Dr Chintan Sheth	(M) +91-9173204454

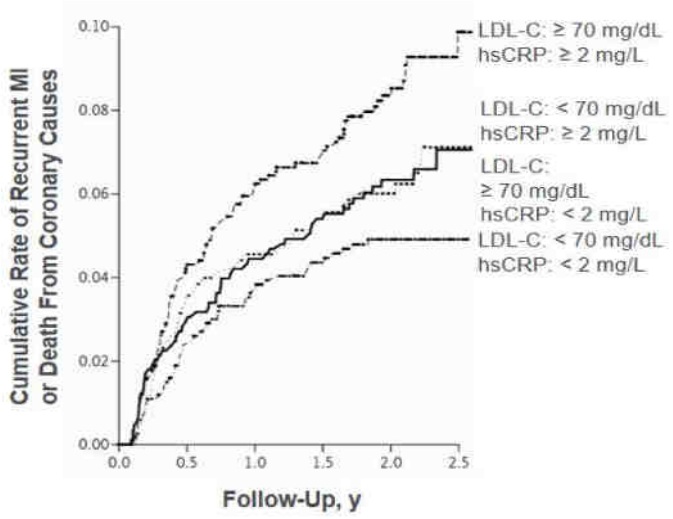
Cardiac Electrophysiologist

Dr Ajay Naik	(M) +91-98250 82666
Dr Hiren Kevadiya	(M) +91-98254 65205

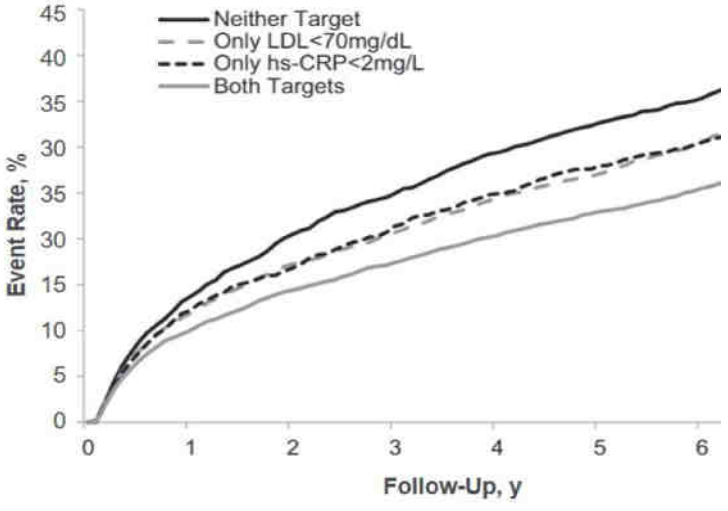
hsCRP should be measured in all patients who undergo secondary prevention:

Once we treat ASCVD patients with current Guideline Directed Medical Therapy (GDMT), the future risk is significantly reduced. At the same time it is important to understand that even after using best possible doses of all GDMT and achieving targets of blood pressure, lipids and GhbA1c, there still remains a residual risk of events. A part of this residual risk is because of CV inflammation, which can be assessed and quantified with measurement of hsCRP. A metanalysis of three recent trials (PROMINENT, STRENGTH and REDUCE IT) demonstrated that future risk differed based on levels of hsCRP in the patients who achieved target LDL cholesterol. Such a fact was previously demonstrated by PROVE-IT (patients with recent ACS) and IMPROVE-IT (stabilised patients post ACS) trials; event rates were much lowered in the group who achieved both – LDL cholesterol <70 mg/dL and hsCRP < 2 mg/L. Thus, lowering both, LDL cholesterol and inflammation make a great sense for ASCVD risk reduction in secondary prevention patients.

PROVE-IT[1]



IMPROVE-IT[2]

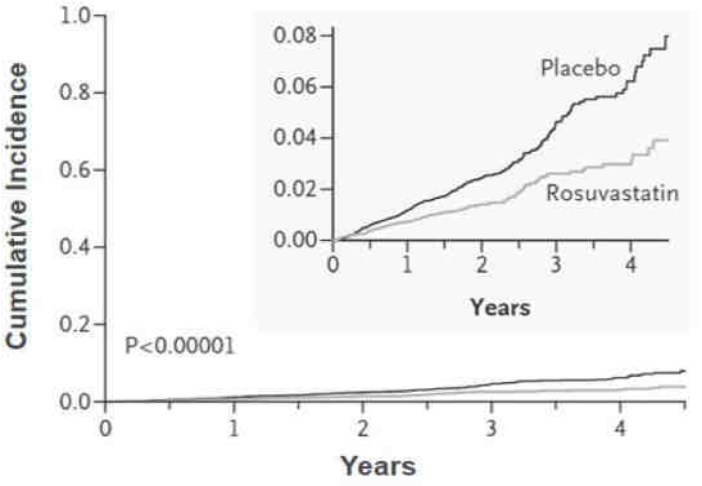


MI myorcardial infarction.

1. Ridker PM. et al; Pravastatin or Atorvastatin Evaluation and Infection Therapy - Thrombolysis in Myocardial Infaction 22(PROVE IT-TIMI 22) Investigators N Engl J Med 2005:352:20-28-2 Bahula EA. at al Circulation 2015:132:1224-1233.

In the JUPITER trail, rosuvastatin significantly reduced the incidence of major CVEs in healthy persons without hyperlipidemia but with elevated hsCRP levels

Primary Endpoint



JUPITER Trial Outcomes

Endpoint	HR (95% CI)	*P* Value
Primary endpoint	0.56 (0.46, 0.69)	< .00001
Any MI	0.46 (0.30, 0.70)	.0002
Any stroke	0.52 (0.34, 0.79)	.002
Arterial revascularization	0.54 (0.41, 0.72)	< .0001
Any death	0.80 (0.67, 0.97)	.02

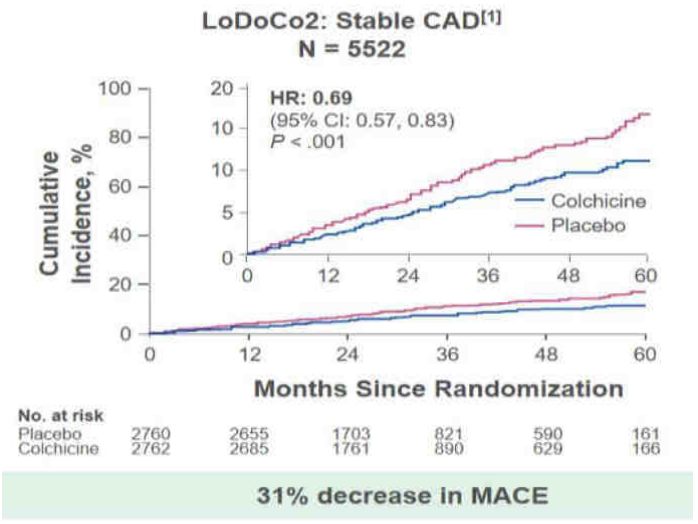
Ridker PM, et al; JUPITER Study Group. N Engl J Med. 2008;359:2195-2207

Contrary to what many believe, hsCRP is a very stable biomarker representing chronic systemic inflammation in

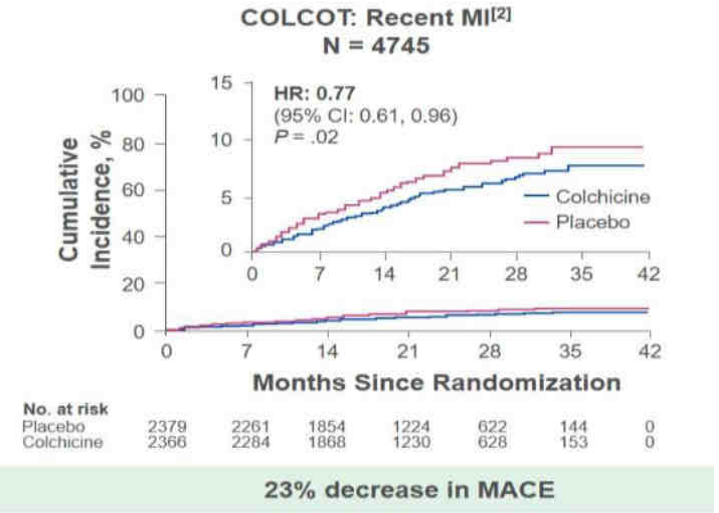
the absence of acute inflammatory insult like infection, injury or acute ischemia. hsCRP level of <1 mg/L is suggestive of low risk of ASCVD, level of 1-3 mg/L is suggestive of mild to moderate risk and likewise, level > 3 mg/L is suggestive of high future risk of ASCVD. An hsCRP level of > 10 mg/L is likely to be due to passing infection, under such circumstances, test should be repeated after 6 weeks.

We now have therapies that lower CV risk in patients with high levels of hsCRP:

JUPITER trial demonstrated that Rosuvastatin reduced CV events in people with high level of hsCRP, even if LDL c



31% decrease in MACE

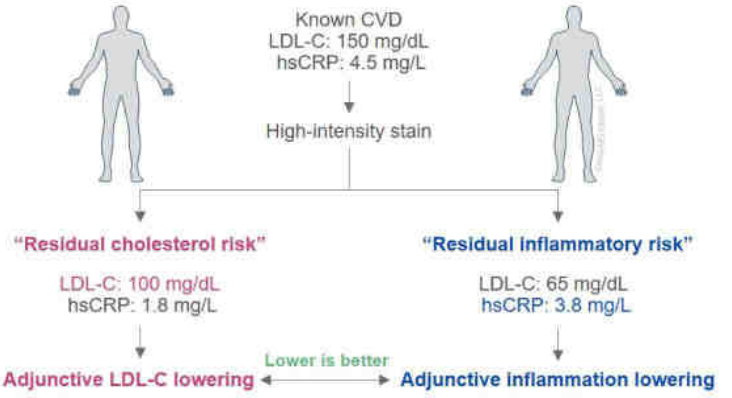


23% decrease in MACE

holesterol was normal as per contemporary guidelines. Use of another lipid lowering molecule, Bempedoic Acid also showed the similar pattern of results.

An old nonspecific anti-inflammatory medicine Colchicine has shown some promising results in recent times.

Two large RCTs (LoDoCo-2 in stable CAD patients and COLCOT in patients with recent MI) showed very significant reduction in major adverse CV events when Colchicine 0.5 mg daily was added over and above GDMT in patients with elevated levels of hsCRP. Totality of evidences does suggest there is reduction in MACE, with some increase in non-cv death, infections and admissions; and no change in overall



mortality.

Lower is better for LDL Cholesterol as well as inflammation:

For every secondary prevention patient, with the use of maximum tolerated dose of statin, ezetimibe and other

lipid lowering molecules an LDL cholesterol level of < 55-70 mg/dL should be targeted. Once this is attained, hsCRP level should be ordered and is found > 2 mg/L, use of Colchicine should be considered especially in patients with

No effect on renal or liver function, risk of bleeding, wound healing, fertility, pregnancy, neonatal health, cognition; no increase in cancer or serious infection

Risk of bone marrow suppression and myotoxicity increases if used with Clarithromycin, Ketoconazole, Fluconazole, Cyclosporine or Ritonavir especially if eGFR falls < 45 mL/min

polyvascular disease or with recurrent ACS.

Colchicine is quite a safe option; other specific and potentially safer medicines are under evaluation:

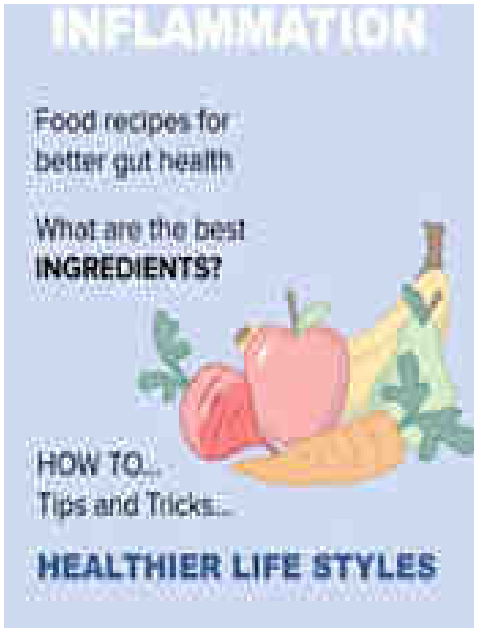
Colchicine can be safely used in patients with normal liver

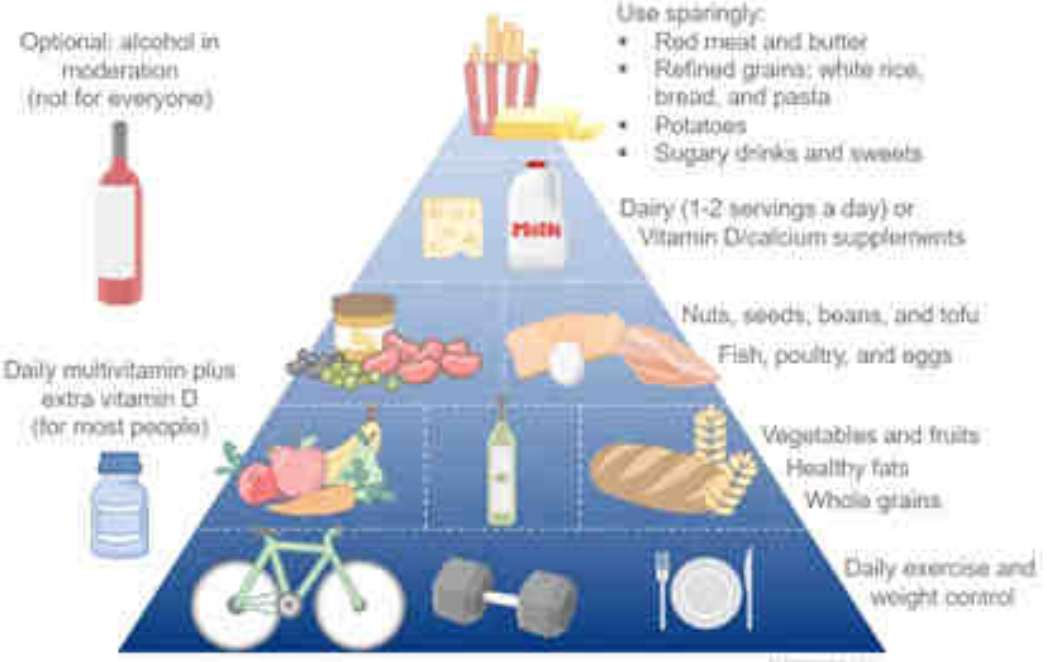
and kidney functions. should not be used or stopped in patients with eGFR <45 ml/min, advanced liver dysfunction or those with ALT / CPK Total > 3x ULN or those with cytopenia.

Injectable Ziltivekimab, a fully human monoclonal antibody to IL-6 has been under extensive evaluation in 3 different groups of patients with ACS, heart failure with preserved EF (HFpEF) and chronic kidney dysfunction (CKD).

It would be prudent to mention that heart-healthy plant-based diet with mindful eating; regular physical and monitored breathing exercises; adequate quality, quantity and timing of sleep; avoiding use of tobacco and other harmful addictive substances and practising mental relaxation techniques including mindful meditation leading to a state of equanimity – all can have very powerful positive impact on cardiovascular and global health, part of which is through anti-inflammatory mechanism.

Never the less, future holds lot of excitement in this context.





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Director - Orthopaedics & Joint Replacement

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For Appointment: +91 99796 92131 | +91 94266 32131 | +91 7926732131

Marengo CIMS Hospital
Off.Science City Road, Sola, Ahmedabad - 380060

JCI (USA)

1800 309 9999

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