Presentazione Documenti in sviluppo con la Società Italiana Ipertensione Arteriosa (SIIA)

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Lipid lowering nutraceuticals in clinical practice: an evidence-based consensus of a large number of Italian scientific societies

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With the endorsement of: Italian Society of Nutraceuticals (SINut), Italian Federation of Hospital Services Directors (FADOI), Italian Toxycology Society (SITOX), Nutrition Foundation of Italy (NFI), Italian Dietetics and Clinical Nutrition Association (ADI), Italian Society of Nutrition Sport and Well-being (SINSEB), Italian Hypertension Society (SIIA), Italian Hypertension Society Foundation (SIIA Foundation), Italian Dietetitian Association (ANDID), Italian Endocrinologist Association (AME), Italian Diabetes Health Care Professionel Association (OSDI), Italian Obesity Society (SIO), Italian Society of Functional Medicine (SIMF), Italian Society of Nutrigenomics and Epigenetics (SINE), Italian Federatiom of Dietary Supplements Producers (FEDERSALUS), Lipid and Blood Pressure Meta-analysis Collaboration (LBPMC)

International Expert and independent supervisor: Prof. Maciej Banach

Member of the European Commission's Scientific Panel for Health (SPH), EAS Advisor in Matters related to EU Relations/Contacts, Founder, Lipid and Blood Pressure Meta-analysis Collaboration (LBPMC) Group

90 pagine, 370 voci bibliografiche …

Pharmanutrition & Functional Foods 2017

Lipid lowering nutraceuticals in clinical practice: position paper from an International Lipid Expert Panel#

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on behalf of the International Lipid Expert Panel (ILEP)

With the official endorsement of:
Austrian Atheroclerosis Society (AAS)
Baltic Atherosclerosis Society
Belgian Atheroclerosis Society
Croatian Atherosclerosis Society
Czech Atherosclerosis Society
Hellenic Atherosclerosis Society
Hungarian Atherosclerosis Society
Italian Society of Nutraceuticals (SINut)
Kosovo Society of Caridology
Lipid and Blood Pressure Meta-Analysis Collaboration (LBPMC) Group
Polish Lipid Association (PoLA)
Romanian Society of Cardiology
Russian National Atherosclerosis Society
Serbian Association for Arteriosclerosis, Thrombosis and Vascular Biology Research
Slovak Association of Atherosclerosis
Slovenian Society of Cardiology
Ukrainian Atherosclerosis Society

Arch Med Sci 2017; 13(5): 965-1005

Nutr Rev. 2017; 75(9):731-767.

Lipid lowering nutraceuticals in clinical practice: an evidence based consensus

<u>Classe A, Evidenza I (singoli componenti):</u> Riso rosso fermentato, Berberina, Fitosteroli, Fibre solubili, Omega-3 (EPA/DHA), Semi di lino, Frutta secca

<u>Classe A, Evidenza I (associazioni):</u> Riso rosso fermentato + Berberina, Riso rosso fermentato + Omega 3, Riso rosso fermentato + Fitosteroli

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The new documents … work in progress!

- **Nutrients and nutraceuticals for the management of high normal blood pressure: an evidence-based consensus document**

- **Non pharmacological treatment of asymptomatic hyperuricemia**

Nutrients and nutraceuticals for the management of high normal blood pressure: an evidence-based consensus document

- **Largely prevalent risk factor**
- **Linear relation between BP reduction and CV risk reduction (especially in adults)**
- **Unmet need of patients**
- **Large support from clinical literature**

Nutraceuticals and BP: a large literature background

- Borghi C, Cicero AF. Nutraceuticals with a clinically detectable blood pressure-lowering effect: a review of available randomized clinical trials and their meta-analyses. Br J Clin Pharmacol. 2017 Jan;83(1):163-171. doi: 10.1111/bcp.12902.

- Sirtori CR, Arnoldi A, Cicero AF. Nutraceuticals for blood pressure control. Ann Med. 2015;47(6):447-56. doi: 10.3109/07853890.2015.1078905.

- Cicero AF, Colletti A. Nutraceuticals and Blood Pressure Control: Results from Clinical Trials and Meta-Analyses. High Blood Press Cardiovasc Prev. 2015 Sep;22(3):203-13.

Level of evidence	Definition
Level A	Data derived from multiple methodologically correct randomized clinical trials or their meta-analysis
Level B	Data derived from a single randomized clinical trial or large non-randomized clinical studies
Level C	Consensus or opinion of the experts and/or small studies, retrospectives studies, registries

Class of recommendation	Definition	Suggested wording to use
Class I	Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, effective	Is recommended/Is indicated
Class II	Conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of the given treatment or procedure	
Class IIa	Weight of evidence/ opinion is in favour of usefulness/efficacy	Should be considered
Class IIb	Usefulness/efficacy is less well established by evidence/opinion	May be considered
Class III	Evidence or general agreement that the given treatment or procedure is not useful/effective and in some cases may be harmful	Is not recommended (no efficacy on lipid profile)

What is supported by meta-analyses ?

• **PUFAs**	High dosages, high costs, ADRs	↓
• **Isoflavones**	Limited to peri-menopausal women	↓↓
• **Lactotripeptides**	Limited to Asians, high cost	-/↓↓
• **L-Arginine**	High dosages, ADRs	↓↓
• **Potassium**	Risk in CKD	↓
• **Chelated Mg**	Risk in CKD	↓
• **Calcium**	Limited to pregnancy	↓
• **Vitamin C**	High variability of available formulation	↓
• **Cocoa flavonoids**	High cost, low palatability	↓
• **Pomegranate juice**	High cost	↓↓
• **Beet juice**	Low palatability, high dosages	↓↓
• ***H. sabdariffa* teas**	Trials not replicated outside Middle-East	↓↓
• **Coenzyme Q10**	Limited to hypertensives, high dosages	↓↓
• **Lycopene**	High dosages, high costs	↓↓
• **CR melatonin**	Legal problems, Limited to night hypertension	↓↓
• **Aged garlic extract**	ADRs	↓

Clinical evidence limitation

- **Small studies**
- **Short-term studies**
- **Lack of data on home BP and ABPM**
- **Lack of data on FMD/PWV (beyond some ingredients)**
- **Lack of data on hard outcomes**

Non pharmacological treatment of asymptomatic hyperuricemia

- **Largely prevalent risk factor**
- **No drugs active/safe on midly increased SUA level**
- **Unmet need of patients**

Clinical evidence limitation

- **Few small studies**

- **Short-term studies**

-> Suggestion based on expert opinion

The next step

- **In coauthorship with the Lipid and Blood Pressure Meta-analysis Collaboration Group:**

- **Nutraceuticals in support to QoL in heart failure patients: an EBM approach**