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Review

Can FSMP Salt Substitutes Support Antihypertensive Therapy in Mild-to-Moderate Hypertension? A Narrative Review of Rationale, Evidence, Safety, and Regulatory Implications

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Abstract: Aims. Arterial hypertension remains one of the leading modifiable cardiovascular risk factors worldwide, and its management requires the integration of pharmacological treatment with evidence-based lifestyle and dietary measures. Among non-pharmacological approaches, sodium reduction is strongly recommended, although long-term adherence to a low-salt diet is often limited by reduced palatability. In this context, low-sodium, potassium-enriched salt substitutes, including products classifiable in specific settings as foods for special medical purposes (FSMP), have emerged as a potentially relevant adjunctive strategy for the dietary management of selected hypertensive patients. Data Synthesis. This narrative review specifically examines low-sodium, potassium-enriched salt substitutes intended for the dietary management of arterial hypertension, with emphasis on their compositional rationale, mechanisms of blood pressure reduction, regulatory framework, clinical efficacy, safety profile, and practical applicability. Available evidence from randomized trials and meta-analyses indicates that these products can reduce systolic and diastolic blood pressure and, in some settings, improve cardiovascular outcomes and all-cause mortality. However, the strength of the evidence is tempered by heterogeneity in study populations, formulations, background diets, and healthcare settings. In addition, the risk of hyperkalaemia remains a clinically relevant concern, especially in patients with chronic kidney disease, diabetes mellitus, adrenal insufficiency. Conclusions. Low-sodium, potassium-enriched salt substitutes should be regarded not as a replacement for standard antihypertensive therapy in most patients, but as a potentially effective adjunct, and in selected mild-to-moderate cases a possible supportive alternative within a medically supervised care pathway. Future research should better define which patient groups derive the greatest net clinical benefit and how these products can be integrated into different regulatory and healthcare contexts.

Keywords: arterial hypertension; salt substitutes; FSMPs; hyperkalaemia; cardiovascular prevention

1. Introduction

Arterial hypertension is one of the main cardiovascular risk factors worldwide, and its management requires an integrated therapeutic approach that combines pharmacological and non-pharmacological interventions [1]. Despite advances in antihypertensive therapy, substantial gaps remain in optimal blood pressure control in the

general population. In this context, non-pharmacological measures play a key complementary role [2], contributing both to further reductions in blood pressure values and to decreased need for antihypertensive drugs and their potential adverse effects. Among non-pharmacological dietary interventions, sodium restriction has emerged as a strategy of particular clinical relevance [3,4]. However, long-term adherence to low-sodium diets is often poor due to changes in food palatability, which has prompted the development and study of low-sodium salt substitutes, classifiable as foods for special medical purposes (FSMPs), in which sodium chloride is partially replaced by potassium chloride. These products, to be used under medical supervision in accordance with European regulations (EU Regulation 609/2013 and EU Regulation 2016/128), offer an alternative approach to reduce sodium intake while preserving palatability. In fact, although they are often discussed simply as instruments for sodium reduction, their potential clinical value lies in a more complex combination of reduced sodium intake, increased potassium exposure, preserved palatability, and relatively easy incorporation into daily food preparation. This review does not aim to cover all dietary approaches to hypertension, nor all categories of foods for special medical purposes used in cardiovascular care. Rather, it focuses specifically on low-sodium, potassium-enriched salt substitutes indicated for the dietary management of arterial hypertension. The objectives are fourfold: first, to examine their compositional and physiological rationale; second, to summarize and critically appraise the available clinical evidence on blood pressure and cardiovascular outcomes; third, to discuss the main safety concerns, particularly hyperkalaemia and its determinants; and fourth, to analyse the regulatory and implementation implications relevant to their use in clinical practice. By narrowing the scope in this way, the review seeks to provide a more coherent and clinically useful synthesis of a rapidly developing field.

Methodology

A narrative review of the scientific literature on the topic was conducted. The search query set on the database included the terms “arterial hypertension”, “salt substitutes”, “FSMP”, “adverse event”, “side effect2” and the words “AND”, “OR”, “NOT”. On this basis, only the studies that presented the evidence most relevant to the research aim were selected for the analytical comments.

2. Salt Substitutes: Composition and Rationale

Low-sodium salt substitutes represent an alternative to simple restriction of common salt intake, overcoming the problem of reduced palatability associated with low-salt diets [3,4]. These products maintain organoleptic properties similar to regular salt, thereby minimizing the impact on the taste of foods. The formulation most frequently used in salt substitutes consists of a mixture of 75% sodium chloride and 25% potassium chloride, although the proportions may vary across products, and some formulations also contain magnesium sulphate [3–5]. According to European regulations, these salt substitutes can be classified as FSMPs, intended for the dietary management of patients with specific clinical conditions and to be used under medical supervision. Their use provides a dual pharmacological advantage: a reduction in sodium intake and a concomitant increase in potassium intake. Increased potassium intake exerts an independent and additive blood pressure-lowering effect by promoting renal sodium excretion and modulating vascular reactivity, thereby reducing peripheral resistance [6]. Under European legislation, FSMPs are classified as foods for specific groups and are designed to meet the particular nutritional needs. The distinctive requirement of an FSMPs lies in its ability to meet the nutritional needs imposed by a medical condition. In recent years, several FSMPs products have been developed and marketed in the European Union for the dietary management of hypertension. According to European guidelines, low-sodium salts are defined as salt substitutes with a sodium chloride content between 20% and 35%, corresponding to a sodium content between 7.8 and 13.6 g% [7]. The potassium-to-sodium ratio must be at least 1.5:1, whereas sodium-free salts are defined as salt substitutes devoid of sodium chloride, with residual sodium content not exceeding 120 mg/100 g [7]. Among European countries, Italy has established a national register listing FSMPs that can be reimbursed for patients whose conditions fall within national or regional essential levels of care [2]. Table 1 illustrates FSMPs available at the expense of the National Healthcare System (NHC) in Italy according to the national register, together with their indications and marketing price.

Table 1. FSMPs indicated for the dietary management of arterial hypertension and other medical conditions requiring marked reduction of dietary sodium intake, placed on the market in the EU and made available at the expense of the NHC in Italy according to the national register (information consulted on the Italian Codifa® database on 15 December 2025).

FSMP	Type of Salt	Indication	Marketing Price per Unit
Novosal sale iposodico 300 g®	Low sodium	Dietary management of arterial hypertension and other medical conditions requiring marked reduction of dietary sodium intake	€ 5.90
SALE IPOSODICO IODATO BENE.SI' COOP (200 g)®	Low sodium	Dietary management of arterial hypertension and other medical conditions requiring marked reduction of dietary sodium intake	Not available
SALE IPOSODICO IODATO 200 g PIACERSI CONAD®	Low sodium	Dietary management of arterial hypertension and other medical conditions requiring marked reduction of dietary sodium intake	Not available
SALE IPOSODICO IODATO BONOMELLI ®	Low sodium	Dietary management of arterial hypertension and other medical conditions requiring marked reduction of dietary sodium intake	Not available

3. Mechanistic Basis of Blood Pressure Reduction

The antihypertensive effect of low-sodium, potassium-enriched salt substitutes cannot be explained solely by a generic reduction in salt intake. It reflects the interaction of at least three complementary mechanisms: lower sodium exposure, higher potassium intake, and improved adherence compared with strict sodium restriction alone [8]. This distinction is important, because it supports the view that salt substitutes are not simply a behavioural recommendation, but a structured nutritional intervention with identifiable physiological effects. Reduction in dietary sodium lowers extracellular fluid expansion, decreases sodium-sensitive increases in blood pressure, and reduces vascular stiffness and peripheral resistance [9]. These effects are particularly relevant in older adults, in patients with established hypertension, and in salt-sensitive individuals, who tend to experience larger blood pressure reductions after sodium restriction. At the same time, increased potassium intake may exert an independent blood pressure-lowering effect through several pathways. Potassium promotes natriuresis, modulates the renin-angiotensin-aldosterone system, improves endothelial and vascular smooth muscle function, and may attenuate sympathetic and vasoconstrictive responses [10]. The combined reduction in sodium intake and increase in potassium intake therefore provides a biologically plausible explanation for the greater effect of salt substitutes compared with sodium restriction advice alone. A further practical mechanism is improved long-term adherence. One of the major limitations of conventional low-sodium diets is reduced palatability, which often compromises sustained implementation in routine care. By preserving a taste profile closer to that of common salt, low-sodium salt substitutes may help maintain dietary adherence over time and thereby enhance the real-world effectiveness of sodium reduction strategies. This implementation-related mechanism is clinically relevant, because an intervention with modest physiological efficacy but high adherence may produce greater population benefit than a theoretically stronger intervention that patients do not follow consistently. From a clinical perspective, these mechanisms also help explain why the net effect of salt substitutes may vary across populations. The magnitude of benefit likely depends on baseline sodium intake, background dietary potassium, renal function, age, degree of salt sensitivity, use of concomitant antihypertensive therapy, and the specific formulation employed. For this reason, mechanistic plausibility should not be interpreted as evidence of uniform benefit across all patient groups, but rather as a framework for understanding both efficacy and its limits in practice.

4. Evidence on Efficacy

The blood pressure-lowering efficacy of sodium restriction depends on multiple factors, including baseline blood pressure, age and presence of hypertension [11]. The relationship between sodium intake and blood pressure shows a clear dose-response pattern, with greater reductions in hypertensive and older subjects, who therefore derive particular clinical benefit from sodium restriction. Observational and interventional studies consistently demonstrate that reduced sodium intake is associated with lower blood pressure values. A large meta-analysis of 133 interventional studies including 12,197 participants provided conclusive evidence of the blood pressure-

lowering effect of sodium restriction [12]. On the contrary, some observational studies reported a J-shaped association between sodium intake and mortality, suggesting increased risk at both high and very low sodium intakes [13]; however, this paradox can largely be explained by reverse epidemiology, since very low sodium intake is often observed in patients with severe chronic diseases and low overall food intake, and the J-curve tends to disappear after adjustment for pre-existing cardiovascular conditions. The most robust evidence on salt substitutes comes from the large randomized controlled trial carried out by Neal et al., which enrolled 20,995 participants from 600 rural Chinese villages with a mean follow-up of 4.74 years [14]. Villages were randomized to a potassium-enriched salt substitute (75% NaCl, 25% KCl) or regular salt, and the intervention group showed a significant reduction in systolic blood pressure as well as reduced risk of stroke, acute coronary syndrome and all-cause mortality, without a significant increase in clinically relevant hyperkalaemia. In a 3-year trial including 462 participants, the proportion of patients treated with antihypertensive drugs was significantly lower in the salt substitute group compared with the regular-salt group at most time points [15]. Another study reported a significantly reduced use of antihypertensive drugs after three months in the salt substitute group [16]. A third study showed a non-significant trend towards a reduction in the consumption of antihypertensives [17]. A recent randomized double-blind clinical trial evaluating the hypotensive effect of low-sodium salt substitution has shown that this may indeed represent a non-pharmacological therapy for hypertensive patients, demonstrating its effectiveness in reducing systolic blood pressure and diastolic in middle-aged and elderly hypertensive patients [18]. A systematic review and meta-analysis that included 23 randomized controlled trials involving 32,073 patients demonstrated that salt substitutes have a strong effect on reducing BP and all-cause mortality. In the random-effects model, participants taking salt substitutes showed a significant reduction in systolic and diastolic blood pressure compared to participants consuming regular salt, and a significant increase in 24-h urinary potassium, also demonstrating a significant reduction in all-cause mortality [19]. Overall, the blood pressure-lowering effect of salt substitutes can be considered quantitatively equivalent to that of a single antihypertensive agent and is achieved at a substantially lower cost than pharmacological therapy. This makes FSMPs-grade salt substitutes particularly attractive in settings with limited healthcare resources and reduced access to medicines.

Despite the robustness of the available evidence, there are several limitations in interpreting the clinical applicability of salt substitutes. The largest randomized trials have been conducted in specific geographic settings, particularly in rural areas of China, where diet and thus baseline sodium intake, food preparation practices, and access to healthcare may differ substantially from those of other populations. In addition, the studies reviewed are heterogeneous in terms of participant characteristics, baseline cardiovascular risk, concomitant antihypertensive therapy, length of follow-up, and product formulation. Consequently, although the evidence supports a clinically significant blood pressure-lowering effect, the magnitude of benefit and the balance between efficacy and safety may not be fully generalizable to all healthcare systems, dietary cultures, or patient groups. This should be considered when translating study results into routine clinical practice, especially in populations with a higher prevalence of chronic kidney disease, diabetes, multimorbidity, or limited capacity for biochemical monitoring.

Taken together, the available studies support a clinically meaningful blood pressure-lowering effect of low-sodium, potassium-enriched salt substitutes, but the interpretation of this literature requires caution. The strongest evidence comes from large, randomized trials and meta-analyses, yet much of the interventional literature is concentrated in selected geographic areas, particularly rural Chinese settings characterized by high baseline sodium intake, domestic cooking patterns, and epidemiological profiles that may not reflect those of European or other high-income populations. In addition, the interventions are not fully uniform across studies, because the sodium-to-potassium ratio, the presence of additional minerals, the duration of treatment, and the degree of background dietary counselling vary considerably. These sources of heterogeneity make direct comparison difficult and suggest that effect size estimates should not be extrapolated uncritically to all clinical settings. Although some studies suggest reductions in antihypertensive drug use and improvements in hard cardiovascular endpoints, salt substitutes should not be interpreted as a universal replacement for pharmacological therapy. A more balanced interpretation is that they may reduce therapeutic burden or enhance blood pressure control in appropriately selected patients, especially when used as part of a broader management strategy. The clinical question is therefore not whether they can replace antihypertensive drugs in absolute terms, but under which conditions they can provide meaningful additive or partially substitutive benefit without compromising safety.

5. Safety Considerations

Although the incidence of hyperkalaemia associated with salt substitutes is low in large clinical trials, this complication deserves particular attention because it can be life-threatening, presenting with cardiac arrhythmias and sudden cardiac death. The predominant risk factor for hyperkalaemia is impaired renal function, and chronic

kidney disease is the main determinant of hyperkalaemia during potassium supplementation [20]. In China, where most salt substitute trials were conducted, there is a substantial prevalence of undiagnosed chronic kidney disease, underscoring the importance of assessing renal function before recommending these products [21]. Other relevant risk factors include diabetes mellitus, adrenal insufficiency and, especially, concomitant use of drugs that interfere with renal potassium excretion, such as potassium-sparing diuretics, mineralocorticoid receptor antagonists and inhibitors of the renin-angiotensin system. Careful clinical assessment, including evaluation of renal function and current pharmacotherapy, is therefore mandatory before prescribing potassium-enriched salt substitutes. Patient selection should be guided by an individual risk assessment. Potassium-enriched salt substitutes appear to be most appropriate for patients with mild to moderate hypertension, preserved renal function, and the absence of relevant risk factors for hyperkalemia. Conversely, these products should be avoided in patients with advanced chronic kidney disease, baseline hyperkalemia, adrenal insufficiency, or conditions associated with impaired potassium excretion. Particular caution is warranted in patients receiving renin-angiotensin system inhibitors, mineralocorticoid receptor antagonists, potassium-sparing diuretics, or other therapies that may increase serum potassium. Renal function and serum potassium should be assessed before initiating treatment, and monitoring should be repeated after initiation of therapy and periodically thereafter, with closer follow-up in patients at higher risk. Therefore, the safety profile of these products should be interpreted in relative rather than absolute terms. The low incidence of severe hyperkalaemia reported in large trials is reassuring, but it should not obscure the fact that trial participants are often monitored more closely than patients in routine practice. The translation of efficacy data into real-world care depends on the ability of clinicians to identify high-risk patients, assess renal function before use, review concomitant medications, and ensure follow-up monitoring when indicated. As a result, safety is not only an intrinsic property of the product, but also a function of the healthcare context in which it is prescribed and monitored.

6. Implications for Clinical Practice

Overall, the available evidence supports the integration of low-sodium, potassium-enriched salt substitutes into the multimodal management of mild and moderate arterial hypertension [3,4]. When used appropriately, these products can improve blood pressure control and reduce pharmacological burden, with a blood pressure-lowering effect comparable to that of a single antihypertensive drug and additive to conventional therapy. Salt substitutes are particularly useful in patients with mild hypertension who may benefit from an initial non-pharmacological approach, in patients with resistant hypertension who require additional therapeutic strategies, and in settings where access to antihypertensive medicines is limited. Their classification as FSMPs under European regulations is consistent with the need for medical supervision and with the requirement to tailor their use to the individual risk profile of each patient. Figure 1 illustrates the clinical positioning of FSMP-grade low-sodium salt substitutes in hypertension management.

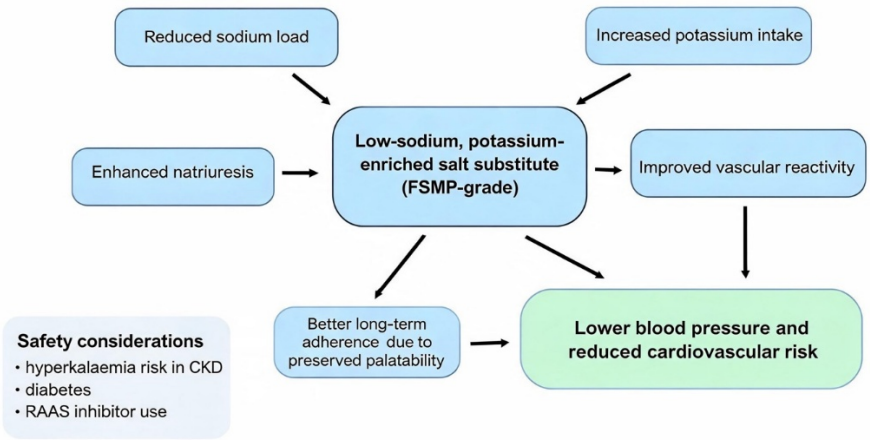

Figure 1. Clinical positioning of FSMP-grade low-sodium salt substitutes in hypertension management.

7. Public Health Strategies and Future Perspectives

At the population level, potassium-enriched salt substitutes represent a promising but not universally transferable intervention. Their public health potential derives from the possibility of achieving sodium reduction without fully sacrificing taste acceptability, thereby improving adherence compared with conventional low-sodium advice. However, the balance between benefit and risk is likely to differ substantially according to the prevalence of chronic kidney disease, patterns of antihypertensive prescribing, habitual dietary sodium intake, food

consumption habits, and the feasibility of biochemical monitoring. From a health systems perspective, implementation cannot be assessed solely on the basis of biological efficacy. Regulatory status, market availability, price, reimbursement pathways, professional awareness, and patient education are likely to influence uptake as much as clinical effect size. This is particularly relevant in Europe, where regulatory classification and reimbursement mechanisms may support medically supervised use, but where consumption patterns often differ from those observed in the largest available trials. In populations where sodium intake derives mainly from processed foods rather than discretionary salt added during home cooking, the impact of household salt substitution may also be attenuated. Another important issue concerns the boundaries of indication. These products are most plausibly positioned as targeted tools for selected patients with mild-to-moderate hypertension or as adjuncts within integrated management pathways, rather than as universal substitutes for antihypertensive medication. Future research should therefore move beyond the simple question of efficacy and focus on patient stratification, implementation models, comparative cost-effectiveness across healthcare settings, and monitoring strategies capable of maximizing benefit while minimizing avoidable harm.

8. Conclusions

Current evidence supports low-sodium, potassium-enriched salt substitutes as a clinically relevant dietary intervention in the management of arterial hypertension, particularly in patients with mild-to-moderate disease and preserved renal function. Their benefit appears to derive from a combination of reduced sodium intake, increased potassium intake, and improved palatability compared with strict sodium restriction, which together may favour better blood pressure control and, in some settings, improved cardiovascular outcomes. At the same time, the available evidence does not justify presenting these products as a straightforward replacement for conventional antihypertensive drugs in routine practice. The literature is encouraging, but it is also heterogeneous in terms of populations, formulations, healthcare contexts, and monitoring conditions. As a result, the role of these products is better understood as adjunctive, and only in selected cases partially substitutive, within a medically supervised and individualized treatment strategy. Their use requires attention to contraindications and to the risk of hyperkalaemia, especially in patients with chronic kidney disease, diabetes mellitus, adrenal insufficiency, or exposure to drugs that impair potassium excretion. Careful patient selection, baseline evaluation of renal function and concomitant therapy, and appropriate follow-up monitoring remain essential prerequisites for safe use. Overall, low-sodium, potassium-enriched salt substitutes should be viewed as a promising component of precision dietary management in hypertension rather than as a universal alternative to drug therapy. Their ultimate clinical and public health value will depend not only on efficacy, but also on context-specific implementation, regulation, access, affordability, and capacity for safe monitoring.

Author Contributions

A.Z.: conceptualization; methodology; writing—original draft, validation. S.V.: writing—review & editing, supervision, validation. All authors have read and agreed to the published version of the manuscript.

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Conflicts of Interest

The authors declare no conflict of interest.

Use of AI and AI-Assisted Technologies

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