Double blind, randomized, cross over, controlled clinical trial of Symbiosal on high blood pressure parameters in association with diet and lifestyle recommendations

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Study context:
Most of hypertensive patients have difficulties to reduce salt intake and we studied an association of Chitosan with NaCl according a specific chemical procedure which could reduce the hypertensive power of the CI.

Main objective:
The main objective was to compare the decrease of the high blood pressure parameter with Symbiosal (NaCl + Chitosan 3%) and with NaCl during the diet and lifestyle improvement period which must be prescribed to the patient before an eventual antihypertensive treatment.

Secondary objective:
The secondary objectives were to compare between groups the patient’s compliance to salt-restricted diet and the symbosial (NaCl + Chitosan 3%) tolerance.

Study design:
Double blind, randomized, cross over, controlled clinical trial of Symbiosal (NaCl + Chitosan 3%) vs NaCl on two groups of 20 patients during two periods of 8 weeks.

Inclusion criteria:
Men and women older than 18 years presenting a mild hypertension defined by a SBP between 140-159 mmHg and a DBP between 90-99 mmHg and having never been treated with an antihypertensive drug.

Results:
40 patients were included in the ITT analysis.
The effect of Symbiosal appeared as soon as the first period of the cross over showing a decrease of the Systolic Blood Pressure (SBP) from 149.2 ± 4.9 mmHg to 136.1 ± 9.5 mmHg in patients for which Symbiosal was available (decrease of 13.1 ± 10.8 mmHg versus a decrease from 149.7 ± 4.6 mmHg to 142.9 ± 7.7 mmHg in patients for which Symbiosal

High Blood Pressure was controlled (SBP≤140 and DBP≤90) in respectively 76.2% (16/21) vs 36.8% (7/19) (p=0.0119).

The cross over analysis on the two periods confirmed the results showing significant time effect (p=0.0006) and treatment effect (p=0.0156) concerning SBP either for DBP: time effect (p<0.0001) and treatment effect (p=0.0286).

Conclusion:
Switching traditional NaCl by Symbiosal significantly contributes to a better control of hypertension in association to the lifestyle and diet recommendations and may delay the prescription of antihypertensive drugs.

DBP mean value (mmHg) evolution between W0 and W8 (W0 - W8)

Percentage of patients with blood pressure under control at the end of first period

The salt intake was relatively moderate in both groups when compared to the standard patients’ intake and comparable between Symbiosal and traditional salt: 2.9 ± 1 g/d vs 3.0 ± 1.5 g/d (p=0.9412 NS). Any side effect was reported.

Similar results were observed with Diastolic Blood Pressure (DBP) with a decrease of 11.2 ± 7.4 mmHg (p=0.7302) and having never been treated with an antihypertensive drug.

Conclusions:

- The effect of Symbiosal appeared as soon as the first period of the cross over showing a decrease of the Systolic Blood Pressure (SBP) from 149.2 ± 4.9 mmHg to 136.1 ± 9.5 mmHg in patients for which Symbiosal was available (decrease of 13.1 ± 10.8 mmHg versus a decrease from 149.7 ± 4.6 mmHg to 142.9 ± 7.7 mmHg in patients for which Symbiosal could reduce the hypertensive power of the Cl.

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- Switching traditional NaCl by Symbiosal significantly contributes to a better control of hypertension in association to the lifestyle and diet recommendations and may delay the prescription of antihypertensive drugs.