Paper of Dr F.Kozisek 2014

Effects of drinking water hardness were most frequently studied due to cardiovascular diseases. The most comprehensive review of these studies was commissioned by the Drinking Water Inspectorate of England and Wales and completed by the University of East Anglia in 2005 (Catling et al 2005). The initial search identified 2096 papers. Papers were retained if they presented primary data of human studies, were directly related to the research question (to review and critically assess the merits of available studies concerning the health effects of soft and softened water on cardiovascular disease and cancer) and involved a comparison of populations or individuals at different levels of exposure. Experimental animal studies and human dietary studies were excluded from this review. Overall, 132 studies were identified as primary data papers, of which 17 papers were excluded due to their descriptive but non-analytical content. A total of 115 underwent full article appraisal by two independent reviewers.

The majority of studies reviewed were of an ecological study design. Further study quality criteria were applied to categorise the ecological studies by high, medium or low quality. A total of 60 such papers were evaluated, of which 44 met the minimum quality criteria. Of the 12 high quality studies, 9 presented evidence for a significant inverse association between water hardness, calcium and/or magnesium levels and cardiovascular mortality. The remaining 3 studies found no significant association. Of the 32 medium and low quality studies, 22 found a significant inverse association. Ecological studies are currently considered to provide only limited evidence as individual exposure is not assessed, but they bring additional supporting information to more advanced studies.

Regarding the more advanced epidemiological studies (cross-sectional studies, case control studies, and cohort studies), they brought following results. Five cross sectional studies were identified, of which only 2 sampled the drinking water quality at the individual level with the remainder using an ecological measure of the drinking water parameters. These papers examined individual level cardiovascular risk factors with an inverse association between drinking water calcium and/or magnesium and blood pressure and serum lipids observed in some, but not all studies. Six case control studies examined both drinking water magnesium and calcium and risk of death from cardiovascular disease. Of these, 4 found a significant inverse association with magnesium concentrations. Of 3 cohort studies reviewed, 2 were of medium/poor quality and used an ecological measure of drinking water factors and limited or non-existent controlling for possible confounders. The third study was conducted in Great Britain and found no association between drinking water hardness and cardiovascular disease. However this study also suffered from poor exposure characterisation.

Subsequent systematic review and meta-analysis of 14 analytical observational studies (i.e. the most valid epidemiological studies) investigating the association between cardiovascular disease and drinking water hardness brought convincing epidemiological evidence about protective role of magnesium in drinking water as a pooled odds ratio showed a statistically significant inverse association between magnesium and cardiovascular mortality (OR 0.75 (95%CI 0.68, 0.82), p , 0.001). It means that the highest exposure category (people consuming drinking water with magnesium 8.3 – 19.4 mg/l) was significantly associated with a decreased likelihood of cardiovascular mortality (by 25%), compared with the baseline, i.e. people using water with Mg content of 2.5 – 8.2 mg/l (Catling et al., 2008). Protective role of water calcium towards cardiovascular disease was also confirmed by some studies, but the evidence is not such strong as for magnesium (Catling et al., 2008).

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Contrary to beneficial effects, there is no evidence about any harmful health effects if calcium is present in drinking water below 200 mg/l and magnesium below 100 mg/l. Perhaps only a high magnesium

content (hundreds of mg/l) coupled with a high sulphate content (above 500 mg/l) may cause transient diarrhoea (WHO, 2011a). Nevertheless, such cases are rather rare.
...

Considering high number of epidemiological studies confirming beneficial effects of certain amount of Ca and Mg in drinking water and multitude supporting evidence from experimental and clinical studies, as well as zero health risk relating to usual levels found in drinking water (dozens of mg/l), it is surprising to see the restrained attitude of the World Health Organization (WHO) over the last 20 years to recommend any guideline value. It is surprising if we realize that in 1970s and 1980s the WHO acknowledged importance of water hardness for population health. One can just try to guess the true motives behind current WHO position. And it is even more surprising to read background documents (Hardness in Drinking-water) for development of WHO *Guidelines for Drinking-water Quality* from 1996 (WHO, 2006) to 2011 (WHO, 2011b) and to find that methodically poor epidemiological studies are referred to support importance of water hardness, while advanced studies are mentioned only as footnote or omitted at all (not speaking about supporting animal experimental studies or clinical studies which are also not taken into account), and to read conclusion: "*Although there is some evidence from epidemiological studies for a protective effect of magnesium or hardness on cardiovascular mortality, the evidence is being debated and does not prove causality. Further studies are being conducted. There are insufficient data to suggest either minimum or maximum concentrations of minerals at this time, and so no guideline values are proposed.*" (WHO, 2011b).

This view is in contrast to the statement of two prominent epidemiologists R. Calderon and P. Hunter who concluded their chapter on epidemiological studies and the association of cardiovascular disease risks with water hardness in the WHO monograph on Ca and Mg in drinking water: "*Information from toxicological, dietary and epidemiological studies supports the hypothesis that a low intake of magnesium may increase the risk of dying from, and possibly developing, cardiovascular disease or stroke. Thus, not removing magnesium from drinking-water, or in certain situations increasing the magnesium intake from water, may be beneficial, especially for populations with an insufficient dietary intake of the mineral. This raises a significant policy issue. How strong does the epidemiological and other evidence need to be before society acts to reduce a potential public health threat rather than await further evidence that such a threat is real? Such a decision is a political rather than a purely public health issue. There is a growing consensus among epidemiologists that the epidemiological evidence, along with clinical and nutritional evidence, is already strong enough to suggest that new guidance should be issued.*" (Calderon & Hunter, 2009).

It seems that a deficiency of calcium and magnesium in drinking water poses at least comparable health risk as exceeding the limit for some toxic substances does (which are regulated even the evidence of their toxicity is much less convincing than evidence of beneficial effect of Ca or Mg), nevertheless, precautionary principle is not applied by the WHO in the case of calcium and magnesium, or at least magnesium, where the evidence is much stronger.

Introduction of regulatory measures concerning the minimum levels of calcium and magnesium in drinking water seems to be justified and highly desirable. They should be based on the fact that it is much simpler and much more effective to keep the existing Ca and Mg drinking water levels than to add these minerals to water artificially. Practically, this means restricting the use of technologies leading to removal of Ca and Mg from water only to the cases where the Mg and Ca levels are too high (i.e. of hundreds of mg/l or more) provided that the required minimum of Σ Ca+Mg is kept in the water after treatment. A certain requirement for the minimum required concentration of hardness ($\geq$ 60 mg/l as calcium or equivalent cations) for softened and desalinated water, set up in Council Directive 80/778/EEC (EC, 1980) appeared obligatorily in national legislation of all EEC members in the past. Nevertheless, this Directive

was in force only to December 2003, since Directive 98/83/EC replaced it since 1998 (EU, 1998). The latter directive does not present any requirement for the Ca and Mg levels or water hardness (apart from the lower limit for pH ≥ 6.5 which requires indirectly a certain level of dissolved solids); on the other hand, it does not prevent the member states from implementing such a requirement, if needed, into their national legislation.

Nevertheless, apart from above mentioned WHO approach and EU Drinking Water Directive (98/93/EC), more than 10 European countries have established some form of minimum requirements on hardness level after softening or generally optimum range (e.g. Austria, Belgium, Czech Republic, Denmark, Germany, Hungary, Italy, Netherlands, Poland, Slovakia, Sweden, Switzerland).
Some countries have these requirements legally based, while others issued just recommendation in form of technical standard or guidelines. Other countries try to educate the consumers through information leaflets or websites how to use any softening device in respect to keep calcium and magnesium in water for drinking and cooking purposes (UK).

Selected references:

Calderon R., Hunter P. (2009) Epidemiological studies and the association of cardiovascular dinase risks with water hardness. In: *Calcium and Magnesium in Drinking-water*; p. 110-144. World Health Organization, Geneva. **THIS MONOGRAPH IS AVAILABLE AT WEBSITE OF the WHO**

Catling L.A., Abubakar I., Lake I.R., Swift L., Hunter P. (2005) *Review of Evidence for Relationship between Incidence of Cardiovascular Disease and Water Hardness*. Drinking Water Inspectorate, London, 142p. **THIS REPORT IS AVAILABLE AT WEBSITE OF Drinking Water Inspectorate (UK)**

Catling L.A., Abubakar I., Lake I.R., Swift L., Hunter P.R. (2008) A systematic review of analytical observational studies investigating the association between cardiovascular disease and drinking water hardness. *Journal of Water and Health* 6:433–442. **THIS PAPER IS ATTACHED**