THE EFFECT OF VITAMIN D SUPPLEMENTATION ON RESPONSE TO HEPATITIS B VACCINATION IN DIALYSIS PATIENTS – AN OPEN LABEL PILOT STUDY



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Introduction and objectives:

Patients with advanced chronic kidney disease or on renal replacement therapy should receive active hepatitis B vaccination (1). A major concern of this vaccination is the impaired response rate up to 50% of the cases.

Vitamin D has an important influence on the body's immune system and modulates both innate and adaptive immunity and regulates the inflammatory cascade. However, there is limited data regarding the influence of Vitamin D supplementation at vaccination time to enhance vaccine response (2). The aim of this study was to evaluate the effect of vitamin D supplementation on the response to hepatitis vaccination in incident and prevalent vitamin D deficient hemodialysis patients. Baseline 25OH vitamin D3 was $14,5 \pm 7,6$ ng/mL in the control versus $13,8 \pm 8,2$ ng/mL in the intervention group and increased to $32,6 \pm 6,9$ ng/mL in the intervention group after 12 weeks of native vitamin D supplementation.

In the intervention group 8 patients (42,1%) achieved an anti-HBs titre ≥ 10 IU/L, defined as seroconversion versus 3 patients (25%) in the control group (n.s.). Seroprotection, defined as anti-HBs titre >100 IU/l was observed in 5 subjects of the intervention group and in 2 patients of the control group (n.s.). The non-responder rate was 57,9% (n=11) in the intervention group and 75% (n=9) among the control subjects.

Methods:

This randomized multicentre open label pilot study was performed in two Austrian dialysis centres. We enrolled 35 incident and prevalent hemodialysis patients naive to hepatitis vaccination with 25 OH vitamin D insufficiency (<30 ng/dl). In the intervention group we administered native vitamin D in a dose of 28 000 IE weekly, until vitamin D levels raise >30ng/dl, and hepatitis B vaccination was performed according to protocol (HBvaxPRO 40mcg i.m. months 0, 1, 6) thereafter. In the control group, hepatitis B vaccination was given immediately after inclusion into the study. Anti-hepatitis B-antibody titre (anti-HBs) was measured 8 weeks following the last vaccination.

Results and conclusions:

250H vitamin D3 Baseline (ng/ml)	13,8 ± 8,2	14,5 ± 7,6	n.s.
250H vitamin D3 12 weeks (ng/ml)	32,6 ± 6,9	13,0 ±7,8	<0.001
Seroconversion rate	8/17 (42,1%)	3/12 (25%)	n.s.
Seroprotection rate	5/17 (29,4%)	2/12 (16,7%)	n.s.
Nonresponder rate	9/17 (52,9%)	9/12(75%)	n.s.

<u>Tab. 2:</u>

Difference in vaccine response rates after 12 weeks between intervention group and control group.

The supplementation of oral cholecalciferol in dialysis patients

A total of 35 (25 male, 10 female) patients underwent randomization; 17 patients were in the control group and 18 patients were in the intervention group.

	Intervention group (n=18)	Control group (n=17)	Sign.
Age	65,7 ± 14,3	61,1 ± 13,8	n.s.
Body mass Index	29,2 ± 5,3	23,7 ±6,8	n.s.
Gender male	11 (61,1%)	14 (82,3%)	n.s.
Diabetes mellitus	11 (61,1%)	7 (38,9%)	n.s.

<u>**Tab.1**</u>: Baseline characteristics of study group.

shows a trend to better vaccination response after hepatitis B vaccination. However, despite a standardized regimen of hepatitis B vaccination, the non-response rate was still extraordinary high with 52,9% among the intervention group and 75% in controls.

References:

(1) Guidelines for vaccinating kidney dialysis patients and patients with chronic kidney disease; 2012

http://www.cdc.gov/vaccines/pubs/downloads/dialysisguide-2012.pdf

(2) Lang PO, and Aspinall R. Can we translate vitamin D immunomodulating effect on innate and adaptive immunity to vaccine response? Nutrients. 2015 Mar 20;7(3):2044-60

