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The Effectiveness of Hepatitis B Virus Vaccine in End Stage Renal Disease Patients on Hemodialysis

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ABSTRACT:

BACKGROUND:

Immunization and vaccination are the most effective way to prevent transmission of hepatitis B virus and hence the development of acute and/or chronic hepatitis B Viral infection. Patients with end stage renal diseases have lower seroconversion rates compared with those subjects having intact renal function.

OBJECTIVE:

This study aimed to identify the effectiveness of Hepatitis B vaccine and its response in end stage renal disease patients on hemodialysis.

PATIENTS AND METHODS:

A cross-sectional study with some analytic components was done on patients with end stage renal disease on hemodialysis who completed their hepatitis B Vaccine in 4 doses and received hemodialysis in Al Shafaa center in Al Yarmouk Teaching Hospital during 2022.

RESULT:

The study involved 150 patients on hemodialysis who complete the hepatitis vaccine doses, the mean age was 53.2 years,63.3% of them were males, duration of dialysis range from (1-7 years),most of them received 4 vaccine doses 56.7%, the response rate to HB Vaccine was : non responder whose anti HBs Ab titer less than 10 IU/L was 33.3% , poor responder whose Anti HBs Ab titer between 10-100 IU/L was 20%, and good responder with Anti HBs Ab titer more than 100IU/L was 46.7%.

Serum albumin had significant association with response to vaccine, while duration and quality of dialysis, number of vaccine doses, hemoglobulin and S. creatinine did not affect the response rate to vaccine.

CONCLUSION:

The results of response were classified to three groups; 1) non responder whose anti HBs AB titer less than 10 was 33.3%, 2) poor responder whose Anti HBs AB titer between 10-100 was 20%, and 3) good responder with Anti HBs titer more than 100 was 46.7.

A significant association had been found between S. Albumin and the duration of last vaccine of patients with the response rate to hepatitis B vaccine.

KEYWORDS: dialysis, hepatitis B, response, vaccine.

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INTRODUCTION:

Hepatitis B (HB) is the most common cause of viremia and a leading contributor to cirrhosis and liver disease. Half of all instances of hepatocellular carcinoma, the sixth most frequent cancer in the world, are caused by persistent HB virus (HBV) infections. HBV is the most important carcinogenic factor after tobacco. (1)

Liver disease is a significant cause of morbidity and mortality in patients on maintenance dialysis, with hepatitis HBV infection among the important etiologies.

Individuals receiving chronic dialysis face a signi ficant risk of HBV infection, and those with a chronic HBV infection can spread the virus for many years(2).It is estimated that over 350million individuals globally are affected by chronic hep-atitis infection, leading to 520,000 fatalities and 470,000 instances of hepatocellular carcinoma (HCC) each year (3).

In Iraq, patients with end-stage renal disease (ESRD) on dialysis frequently respond less to the hepatitis B (HBV) vaccine than the general population. This lowered response, known as seroconversion, is associated with the patient's overall health, including hemoglobin, calcium, and albumin levels, as well as the duration of hemodialysis. While some studies suggest a good link between these characteristics and vaccine

response, others emphasize the necessity for alternate immunization tactics or the use of adjuvants to improve response rates in this population [4,5].

Nearby countries data like Saudi and Bahraini hemodialysis patient's prevalence of both HBV and HCV were higher of HCV (9.24%) vs. HBV (5.88%) [5].

CDC guidelines recommend separating antigen-positive patients, assigning a dedicated nursing team, and additionally restrict sharing m edications in artificial kidney centers [6].

Currently available hepatitis B (HB) vaccines showed seroprotecting in more than 95% of the vaccinated population [7].

However, certain healthy individuals and those with compromised immune systems do not respond sufficiently to vaccinations. Within these categories, patients with endstage renal disease (ESRD), including those in pre-and hemodialysis stages, are deemed at significant risk for HB infection due to the possibility of cross-contamination through environmental surfaces, disposables, or equipment during hemodialysis treatment. Once infected, approximately 60% of hemodialysis patients will become chronic carriers of the HB surface antigen (HBsAg), heightening the risk of transmission to other hemodialysis patients, healthcare workers, and family, resulting in considerable logistical and practical challenges, such as the need for separate medical equipment and personnel [8]

Efforts to address the weakened immune response in hemodialysis patients have yielded varied outcomes. A strategy of increased dosage with supplemental injections was deemed essen-tial to enhance the response rate in these individuals. [9]

Factors that have been associated with good response to HBV vaccination include young age (<40 years), adequacy of dialysis, and good nutritional status on the other hand, hemoglobin and parathyroid hormone levels, duration of dialysis, and Hepatitis-C virus (HCV) infection did not significantly influence antibody responses to Hepatitis-B immunization. [10].

STUDY OBJECTIVES:

To identify the effectiveness of Hepatitis B vaccine and its response in end stage renal disease patients on hemodialysis.

PATIENTS AND METHODS:

Study design, setting and duration: a cross-sectional study including a convenient sample of one hundred and fifty patients with end stage renal failure who received hemodialysis in Al Shafaa center in Al Yarmouk Teaching Hospital during 2022.

All CKD patient in Shafaa center of dialysis are routinely included in the system of hepatitis B virus vaccination as part of preparation of patients to start hemodialysis, the vaccine offered to all CKD patients existing or new dialysis, and also for pre-dialysis patients, The HBV four doses (double dose) vaccine (40 micrograms per dose) according to the National Immunization Program recommendations, of hepatitis B vaccine in deltoid muscles at 0,1,2, and 6 months

offered to all patients who tested negative for the HBV surface antigen (HBs Ag) and anti-HBs Ab and who had not previously received the HBV vaccination.

Data collection methods: all patients run hepatitis screening test (Anti-HBsAg titers, HBV surface antigen (HBs Ag) and anti-HBs Ab) before starting vaccine program, then vaccine (Euvax B) offered and started at 0,1,2and 6 month intramuscular in deltoid region by out clinic team in Yarmouk Teaching Hospital, and put the patients in regular vaccine schedule.

All patients who complete the last vaccine dose after the duration of 30 days from last dose will be included in the sample and sent for Antibody titer of Anti-HBs Ab. Patients data like age, sex, past medical history, hemoglobin level, serum albumin, blood urea, fasting blood sugar, presence of hepatitis C antibodies, and dialysis modality at the initiation of vaccination.

inclusion criteria : Patients with end stage renal failure on hemodialysis who complete the schedule of HBV vaccination.

Exclusion criteria: patient had HCV infection, patients had HBsAg positive, patients had history of malignancy and/or still on immunosuppressant drugs, and patients with chronic liver disease.

Definition of variables:

Response to vaccination: Anti-HBsAg titers is measured by an ELIZA kit after one month (30 days) of the last dose, according to the level of Anti-HBs Ag titers one month after the final dose injected (non-responders less than 10 IU per L. poor responders the value between 10-100 IU per L and good responders more than 100 IU per L, A high response was those with titers >1,000 lU/L.) [11].

Adequacy of dialysis of single pool KT/V: was calculated by Daugirdas equation=1.2 was 50% ranging from 0.09 to 1.72. [11].

Ethical approval: the study was approved by scientific committee of Al-Shafaa dialysis center and administration of Al-Yarmouk Teaching Hospital, patient consent was obtained before starting the data collection and these data were for pure research purpose.

Statistical analysis: Statistical analysis using the Statistical Package for Social Science (SPSS 23). Descriptive statistics (frequencies, percentage, means and standard deviations) were applied to all demographic, histopathological data. Chi square test for analytic data, p value of less than 0.05 was considered significant.

RESULTS:

This study included 150 CKD patients on hemodialysis ,94 males and 56 females, age range from (21-76 years). 63.3 % of patients less than 5 years of CKD, and most of them 40%less than 2 years of dialysis, with 76.7%had 3 session per week, baseline blood investigation and monitoring had been investigated in this study, details of blood urea, serum creatinine, fasting blood sugar and albumin were illustrated in table 1

Table 1: Demographic and clinical characteristic of the studied sample.

		No	%
Age	Mean±SD (Range)	53.2±16.4	(21-76)
Sex	Male	94	63.3
	Female	56	36.7
Diabetes	Yes	41	26.7
	No	109	73.3
Duration of CKD (years)	<5	94	63.3
	=>5	56	36.7
Duration of dialysis (years)	<2	60	40
	2	49	33.3
	=>4	41	26.7
	Mean±SD (Range)	2.4±1.4	(1-7)
Number of sessions/week	1	4	3.3
	2	30	20.0
	3	116	76.7
Quality of Dialysis (kt/v)	Adequate (=>1.2 Kt/v)	75	50.0
	Not	75	50.0
	Mean±SD (Range)	1.19±0.30	(0.09-1.72)
	Mean±SD	(Range)	
Urea Reduction Ratio (URR)	0.63±0.12	(0.21-0.84)	
PCV(%)	32.0±5.2	(20-47)	
Albumin (mg/dl)	3.89±0.37	(3.20-4.50)	
FBS (mg/dl)	118.9±41.3	(80.0-220.0)	
S.Cr (mg/dl)	8.69±2.69	(4.60-16.00)	

The duration of last vaccine dose was 15.6 months, and most of them 56.7 with 4 doses of vaccine, the results of response were classified to three groups; 1) non responder whose anti HBs AB titer less than 10 was 33.3%, 2) poor responder whose Anti HBs AB titer between 10-100 was 20%, and 3) good responder with Anti HBs titer more than 100 was 46.7. Table 2

Table 2: The doses of vaccine and response rate.

		No	%
Duration since last vaccine dose (months)	<12	71	46.7
	=>12	79	53.3
	Mean±SD (Range)	15.6±12.0	(3-48)
Number of doses	3	64	43.3
	4	86	56.7
Response Rate	Non(Anti-HBs Ab<10)	49	33.3
	Poor (10—100)	30	20.0
	Good (>100)	71	46.7

Regarding association between duration of disease and efficiency of dialysis with response to vaccine, there was no significant association between these variables. Table 3

Table 3: The association between duration of CKD, efficiency of dialysis and response rate to vaccine.

		Response Rate (Anti-HBs)						P value
		None (<10)		Poor (10-100)		Good (>100)		
		No	%	No	%	No	%	
Duration of CKD (years)	<5	39	42.1	10	10.5	46	47.4	0.171
	=>5	10	18.2	20	36.4	25	45.5	
Duration of dialysis (years)	<2	34	58.3	5	8.3	20	33.3	0.188
	2---	10	20.0	15	30.0	25	50.0	
	=>4	5	12.5	10	25.0	26	62.5	
Number of sessions/week	1	-	-	5	100	-	-	0.241
	2	10	33.3	10	33.3	10	33.3	
	3	39	34.8	15	13.0	61	52.2	
Quality of Dialysis (kt/v)	Adequate (=>1.2)	20	26.7	10	13.3	46	60.0	0.331
	Not	29	40.0	20	26.7	25	33.3	
***Significant using Pearson Chi-square test at 0.05 level.**								

A significant association was found between duration of last vaccine and response rate, while the number of vaccine doses had no relation to response rate.

Table 4: The relation between vaccine doses and response rate of vaccine.

		Response Rate (Anti-HBs)						P value
		None (<10)		Poor (10-100)		Good (>100)		
		No	%	No	%	No	%	
Duration since last vaccine dose (months)	<12	35	50.0	-	-	35	50.0	0.024*
	=>12	14	18.8	30	37.5	36	43.8	
Number of doses	3	15	23.1	20	30.8	30	46.2	0.358
	4	34	41.2	10	11.8	41	47.1	
***Significant using Pearson Chi-square test at 0.05 level.**								

Patients follow up during dialysis with continuous serology and blood investigation was also studied, urea, PCV, FBS, Creatinine and quality of dialysis had no significant association with response to vaccine, while Serum albumin had significant association with response to vaccine.

Table 5: Association of renal function tests and other serology to vaccine response and response rate.

	Response Rate (Anti-HBs Ab)			P value
	None (<10)	Poor (10-100)	Good (>100)	
Urea Reduction Ratio (URR)	0.60±0.16 (0.21-0.84)	0.64±0.07 (0.58-0.75)	0.65±0.09 (0.46-0.84)	0.490
PCV	30.10±5.07 (20-37)	31.67±5.09 (22-36)	33.50±5.16 (26-47)	0.288
Albumin	3.71±0.35 (3.2-4.3)	3.68±0.29 (3.2-4.0)	4.11±0.30 (3.7-4.5)	0.006*
FBS	119.2±45.7 (80-197)	119.7±50.9 (90-220)	118.3±36.9 (88-190)	0.997
S. Cr	8.48±2.31 (5.0-11.8)	8.82±2.61 (5.3-12.0)	8.79±3.13 (4.6-16.0)	0.958
Quality of Dialysis (kt/v)	1.10±0.42 (0.09-1.72)	1.21±0.20 (1.05-1.5)	1.24±0.23 (0.74-1.72)	0.502
***Significant using ANOVA test at 0.05 level.**				

DISCUSSION:

hemodialysis patients are known to be at higher risk of hepatitis B infection as they have altered immune response to hepatitis B vaccines [12]. This study evaluated the response to the hepatitis B vaccine in this cohort. In this study of one hundred and fifty ESRD patients in Al Shafaa center of dialysis, their mean age 53.2 years, ranging from (21years) to (76 years) which is slightly lower than the mean age of many studies in UK, [13] This can be explained by the possible improvement in survival of elderly population in more developed countries. The majority of patients in this study underwent 3 sessions of hemodialysis per week with a mean duration of 2.4 years, the quality of dialysis was defined according KDOQI guideline(kt/v=1.2) and it showed that half of those patients had received sufficient dose of dialysis which is comparable to other study S. Ibrahim et al who revealed a quality of dialysis of 1.13. [14]

Regarding factors that may contribute in vaccine response, urea, hemoglobin and albumin levels, all were measured before and after dialysis to calculate the their levels according to the national kidney foundation (0.65), and all of them found to be lower than the recommended slandered levels, these readings could be affected by many factors like, concomitant chronic illness, dehydration, on the other hand albumin level can reflect mainly the nutrition of patient, in addition, many other diseases that may cause hypoalbuminemia could lead to decreased in response to vaccine and cause immune abnormality. [15]

The national kidney foundation had also recommended the duration since last vaccine dose and the number of vaccine doses , the current study revealed the more than half of the patients had received the last vaccine in less than, during this duration the responsiveness of CKD patients to hepatitis B vaccine would be formed ,and this cut point of 12 months had been also used in Cordova et al study when assessed the response to vaccine at 13 months, as this period can assess the patient with transient response to hepatitis b vaccine or can still had good protection after this period. [16] . Regarding the number of vaccine doses, four doses of vaccine are recommended to CKD patient by national kidney foundation which was applied by more than half of the patients in the current study inspire of the recommended vaccine doses schedule in Al Shafaa center is 4 doses at 0,1,2,6 months, this different in doses is due to miss dose from patients, this finding of 3 vaccine doses just in one study S.Eardley et al who also classified the patient into two groups ,patient with 3 vaccine doses and patients group with 4 doses.[17] based on these results , and according to Anti-HBs Ab level ,the good responders to hepatitis b vaccine with Anti-HBs Ab >100 IU were only 46.7% , and the non-responders were one third of patients with a titer of Anti-HBs Ab <10 IU. Previous studies in hemodialysis patients have shown a variable hepatitis-B vaccination response and this range of response close to the range of Cordova et al study which involved hemodialytic patients. [15] The reasons for the poor response of hemodialysis patients to vaccination are multiple, one of the major causes is uremia which impairs antigen presentation to and activation of T cells, and subsequent antibody production. [18] nevertheless, positive seroconversion (antiHBs > 10 IU/mL) does not always warrant protection against HBV infection in dialysis patients. Lombardi *et al* suggested in one of the oldest studies that investigated immunity in hemodialysis patients,

that antiHBs titer of at least 50 IU/mL should be a target level in HD patients. [19]

The duration of CKD, duration of dialysis, quality of dialysis with response rate to hepatitis b vaccine, in current study shows no significant association to response rate to vaccine. The duration of chronic kidney disease had no effect on response rate to vaccine, this result in current study take the whole duration from the diagnosis of CKD till the time of collecting the data (pre dialysis period and post dialysis period).The quality of dialysis Kt/V also has a rule in response rate but in current study has no significant rule in responsiveness to vaccine, this result is agreed with Udomkarnjananun et al that shows no significant association between dialysis adequacy and response rate to vaccine, but in other study dialysis adequacy is probably a globally validated determinant of seroconversion rates[20]. On the other hand, seroconversion rates significantly correlate with renal function. Han et al reported that seroconversion rates in patients with low GFR [21]. While Asan et al study showed that responders to HBV vaccination had significantly higher levels of URR (%) and Kt/V compared to non-responders, this can be explained as the efficient dialysis might lead to an enhanced response because dialysis helps to restore impaired B7-2 (CD 86) expression on monocytes of dialysis patients [22].

A significant association was found between responsiveness to vaccine and patients whose take the last vaccine below 12 months duration with, which indicate that there is transient protection against hepatitis b virus , this result is agree with study of Asan et al which state that losing detectable anti-HBS antibodies within 12 months of receiving their last dose of vaccine.[22].This in contrast to Han et al (21) experience with a three-dose vaccination regime who found that majority of their respondents maintained protective antibody levels to month 24.

The current study had calculated the urea reduction ratio from measuring the urea before and after dialysis session according to daugirdas method, in addition to hemoglobin level , both had no significant association with vaccine, this result is in agreement with other study by Feng Y et al that also found non statistical significant difference with dialysis adequacy and response to vaccine between responder and non-responder patient.[23] on the other hand, higher Serum albumin had a significant association with response rate which reflect that a higher serum albumin was associated with good antibody response to hepatitis b vaccine. This result is in agreement with other study by Kim et al. [24] who had shown that malnutrition that may be manifested by low serum albumin was negatively influencing the response to the HBV vaccine in hemodialysis patients; Also, other study by Hong et al [25] showed that patients with hypoalbuminemia are unable to produce adequate titers of anti-HbsAb, and albumin level as a nutritional marker has been shown to directly affect antibody response to HBV vaccination. The clinical implication of the current results can be briefed in: improved patients' safety, early Identification of Non-Responders, improve infection control in dialysis unit and apply specific management and follow up strategies for those patients.

Limitation: researchers faced in many different situations during the stage of data collection, like some non - complete patients records that recording and tracking vaccination schedules, patients' responses, and/or HBV status over time which might affected the research results.

CONCLUSION:

The results of response were classified to three groups; 1) non responder whose anti HBs AB titer less than 10 was 33.3%, 2) poor responder whose Anti HBs AB titer between 10-100 was 20%, and 3) good responder with Anti HBs titer more than 100 was 46.7.

Response of vaccination against hepatitis B infection in end stage renal disease is affected by many factors, such as serum albumin, duration of last vaccine, while duration of dialysis, quality of dialysis and number sessions had no effect on vaccination response in the current study, nevertheless, future studies with multicenter setting are recommended to find the impact of these factors on response to vaccine.

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