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Vaccination against hepatitis B among prisoners in Iran: Accelerated vs. classic vaccination

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ABSTRACT

Background: Prisoners and injecting drug users are at constant risk of hepatitis B virus (HBV) infection and the classic 6-months HBV vaccination might not provide immunization rapidly enough. In this randomized clinical trial we investigated the efficacy of an accelerated vaccination protocol vs. classic schedule among prisoners in Iran.
Methods: 180 prisoners were randomized into 2 vaccination groups; group A underwent accelerated vaccination at 0, 1, 4 and 8 weeks and group C were vaccinated at 0, 1 and 6 months. Antibody against Hepatitis-B surface-antigen (anti-HBs) was assessed at baseline, one, two, six and eight months after the first vaccine dose using immunoenzymatic assays. Seroprotection was defined as anti-HBs titer of 10 IU/L or more. Anti-HBc and HBsAg were measured at baseline and 8th month to evaluate new HBV infection and failure of vaccination.
Results: Overall compliance was 100% and 90.4% in groups A and C respectively. While seroprotection rate at one month was significantly higher in group A (22.4%) compared to group C (4.7%), in the 8th month 78.8% and 93.4% seroprotection was achieved in groups A and C respectively ($P < 0.002$).
Conclusion: Compared to classic HBV vaccination regimen, an accelerated 0, 1, 4 and 8 weeks vaccination schedule can achieve early seroprotection more rapidly, provides clinically sufficient seroprotection with higher compliance in prisoners and can be suggested in situations that rapid immunization against HBV infection is warranted.

1. Introduction

Hepatitis B virus (HBV) infection is one of the most common causes of acute and chronic hepatitis worldwide and poses a great burden on health systems [1–3]. Chronic infections with HBV might lead to development of hepatocellular carcinoma (HCC), cirrhosis and death [4]. Based on reports by World Health Organization (WHO), it is estimated that annually over 5 million new cases of HBV infection will emerge worldwide and 500,000–1,200,000 deaths will occur due to HBV related complications [5,6].

Mass HBV vaccination program for newborns was implemented in Iran in 1993 leading to dramatic decline in prevalence of HBV infection from 7.2% in 1979 to 2.14%

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in last 5 years [7]. Additionally, a "Nationwide HBV vaccination program for 17 year-old adolescents" has been recently implemented throughout Iran targeting those who were not included in the 1993 mass vaccination program along with 1989–1992-born teenagers [8].

HBV infection is a major health concern in Iran and two decades after start of mass vaccination programs, it still counts as a considerable cause of chronic liver disease in Iran with an estimated HBsAg prevalence of 2.6% [9].

Although nationwide vaccination of children against HBV has proven its efficacy, yet there are several high-risk adult groups that remain vulnerable and prison inmates are among the high risk groups for HBV infection [10,11]. The cause is largely attributed to prisoners' social and behavioral characteristics such as intravenous drug injections or tattooing [11].

Higher incidence of HBV infection has been observed in prisoners with history of injecting drug use compared to those with no such history. Additionally history of injection and needle sharing is significantly associated with HBV infection in prisoners [11].

An investigation by Center for Disease Control and Prevention (CDC) in USA indicated that almost 16% of new HBV cases are injecting drug users and the incidence of HBV infection in this group is estimated to be 10–31 cases per 100 person-years which is significantly higher than overall incidence in general population [12].

Furthermore another report by CDC in USA revealed that almost 30% of those diagnosed with HBV infections have history of imprisonment most of which had also history of injection [13]. Another investigation in Brazilian prisoners estimated the prevalence of HBV infection to be 17.9% with 0.5% carrier rate [14].

Up to our knowledge, there are a few reports on the current status of HBV infection among prisoners in Iran. A recently published investigation has demonstrated that approximately 5.8% of IV drug users in detention in Iran are HBsAg positive and another study in 2003 estimated the prevalence of HBV infection to be 3.8% in prisons [15,16].

Altogether the current status of HBV infection in correctional facilities highlights the need for targeting prisoners for vaccination against HBV.

However classic HBV vaccination schedule (3 doses at 0, 1 and 6 months) might not be applicable to all inmates as they either might be released anytime during this 6-month period or as well develop HBV infections due to high-risk behaviors before achieving proper seroprotection.

Currently different accelerated vaccination protocols have been proposed for HBV vaccination including a 0, 1 and 2 months vaccination regimen and a 0, 1 and 3 week vaccination regimen to name a few [17,18]. Considering prisoners' high risk environment, the efficacy of these protocols on providing sufficient seroprotection along with acceptable compliance in prisoners is to be tested.

In this randomized trial we aim to compare an accelerated HBV vaccination protocol with the classic schedule regarding their efficacy in providing sufficient seroprotection in prisoners in Shiraz, Iran.

2. Materials and methods

2.1. Subjects and samples

This parallel-group randomized clinical trial was performed from June 2006 to July 2007 in Shiraz, the capital of Fars province in southern Iran in a one-year period. A total of 250 subjects were primarily assessed for eligibility to be recruited from 3 prisons and correctional facilities inside Shiraz. Cluster sampling and systematic sampling methods were used to select individuals. The subjects were then informed of the purpose and methods of the investigation and a written consent was obtained from each individual. Subjects were also informed of their anonymity and their right to quit the study at anytime during the process. Those unwilling to participate were eliminated and eventually 180 individuals consented to participate in the study.

The protocol for the research project was approved by Shiraz University of Medical Sciences Ethic Committee. Moreover the protocol design and report is consistent with consolidated standards of reporting trials (CONSORT) statement [19]. Fig. 1 demonstrates the recruitment and randomization process.

A standard questionnaire was designed and expert physicians interviewed prisoners regarding their demo-

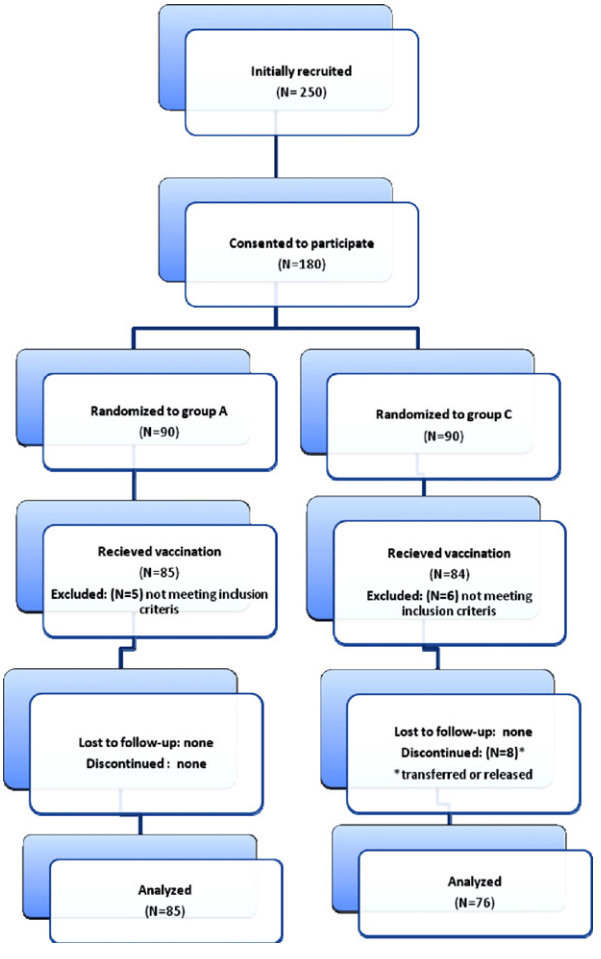

Fig. 1. Overview of participants' recruitment and randomization process.

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graphic data, history of previous viral hepatitis, HIV infection or history of HBV vaccination. Furthermore a baseline antibody against hepatitis B core-antigen (anti-HBc), Hepatitis B surface-antigen (HBsAg) and antibody against hepatitis B surface-antigen (anti-HBs) was measured in all individuals for detection of previous or current HBV infection.

As exclusion criteria those with history of HBV vaccination or HBV infection along with those with positive baseline HBsAg or anti-HBc or positive titers of anti-HBs were eliminated from the study.

2.2. Vaccination protocols

180 subjects approved to participate in this trial and were randomized into two vaccination groups using fixed blocked allocation randomization (groups A and C with 90 participants each).

5 individuals in group A and 6 individuals in group C were tested positive for either of HBsAg, anti-HBc or anti-HBs at baseline and hence were excluded from the study.

The remaining subjects were assigned to one of the two vaccination protocols.

The accelerated HBV vaccination protocol was implemented for individuals in group A (accelerated) which comprised of 4 doses of HBV vaccine in a period of 2 months. The first dose was administered for all individuals in group A at the same time (time zero) and other doses were administered at one, 4 and 8 weeks after first dose. The rationale behind selecting this 2-month accelerated schedule was previous successful implementation of such protocol especially in prison settings [20].

Individuals in group C (classic) were assigned to the classic HBV vaccination protocol which constituted of 3 doses of HBV vaccine at baseline, 1 and 6 months after the first dose. For all individuals of both groups 20 μg of recombinant hepatitis B vaccine was administered at each dose. Vaccination for all individuals in both groups started at the same time and subsequent doses were administered accordingly on the same day for all individuals in each group. Subjects were repeatedly visited and tested for evidence of new HBV infection.

2.3. Laboratory work ups

HBsAg and anti-HBc was measured for detection of acute or chronic HBV infection. Also anti-HBs titer was measured to evaluate the efficacy of different protocols. HBsAg and anti-HBc titers were assessed using immunoenzymatic techniques (Diesse (Enzywell) lab kit, Italy). Enzyme ImmunoAssay (ELISA) for both quantitative and qualitative determination of antibodies to HBsAg (anti-HBs) was performed using DiaPro (Italy) diagnostic kit.

Throughout the trial blood samples were obtained from all individuals for assessment of HBsAg positivity and determination of anti-HBs titer at 5 different time periods. At each point, 10 cm^3 of blood was drawn from each subject and centrifuged at 2000 rpm for 20 min and the sera were tested for anti-HBs and HBsAg. HBsAg and anti-HBs were measured at baseline (before implementation of vaccination protocols), 1, 2, 6 and 8 months after start of each protocol to evaluate the success rate of vaccination in different groups. Anti-HBc was assessed for detection of acute HBV infection at baseline and 8 months after first dose administration. Vaccination failure was defined as serum positivity for anti-HBc or HBsAg at the 8th month. Seroprotection was defined as an anti-HBs titer of 10 IU/L or more.

Compliance rate was defined as the proportion of participants in each group who completed full dose vaccination according to each protocol. Success rate was defined as seroprotection rate measured by intention to treat analysis at the end of the trial which was 8 months after implementation of both protocols.

The primary endpoint of the study was set at 8 months after receiving the first vaccine dose.

2.4. Statistical analysis

Data were analyzed for evaluating the efficacy of immunization in these 3 groups. Changes in mean anti-HBs titers over time and their relationships according to each vaccination group were analyzed using repeated measures. Other demographic data were analyzed and compared using Pearson Chi-square test. P value of <0.05 was considered significant. All analyses were performed using SPSS 11.5 (SPSS Inc., Chicago, IL, USA) study outcome and analysis was primarily based upon per protocol population (those subjects who continued in follow-ups until the endpoint). Furthermore, we analyzed the outcomes based on intention to treat population which included every participant receiving at least one dose of HBV vaccine.

3. Results

Out of 180 male inmates initially recruited for the study, Baseline HBsAg or anti-HBc were tested positive in 3 (1.7%) and anti-HBs was tested positive in 8 (4.4%) subjects (>10 IU/L). Overall 11 subjects were eliminated from the study due to either signs of HBV infection or immunity.

The mean age of the remaining 169 subjects who participated in the study was 34 ± 9.37 years and none of them had self-reported history of HIV or hepatitis C or B infection.

64 subjects (37.8%) had history of previous imprisonment and 15 cases (8.9%) had history of injecting drug use. The detailed demographic features of the participants in each subgroup are gathered in Table 1.

3.1. Compliance

Throughout the study all individuals in group A completed their vaccination schedule in 2 months (100% compliance) while 76 participants completed their vaccine series in group C (90.5% compliance). The rate of compliance in group A (accelerated) was significantly higher than group C ($P < 0.001$).

3.2. Seroprotection

After one month higher seroprotection rate was detected in group A (22.4%) compared with group C (4.7%) $P < 0.001$.

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Table 1
Demographic features of participants.

Demographic characteristics	Group A individuals ($n=85$)	Group C individuals ($n=84$)	P value*
Sex: male	85 (100%)	100%)	>0.05
Marital status: married	43 (55.1%)	25 (30%)	0.002
Age (mean)	36 ± 9.67	36 ± 8.27	>0.05
BMI (mean)	24.28 ± 5.06	24.1 ± 3.98	>0.05
Prior history of incarceration	26 (31%)	32 (37.6%)	>0.05
History of injecting drug use	6 (7.2%)	5 (9.1%)	>0.05
History of unprotected sexual contact (during the last 6 months)	3 (3.6%)	11 (12.9%)	0.04
Tattoo	23 (27.4%)	19 (22.4%)	>0.05
HIV infection	–	–	-
HCV infection	–	–	-
Diabetes	–	–	-

* P value <0.05 is considered statistically significant using Pearson-chi square test.

Table 2
Comparison of Mean antibody titer and seroprotection rates in two vaccination protocols during the course of study.‡

Time Points	Group A (accelerated vaccination) Total number = 85		Group C (classic vaccination) Total number = 84		P value*	
	Mean antibody titer (IU/L)	Seroprotection rate**% (N)	Mean antibody titer (IU/L)	Seroprotection rate % (N)		
Baseline	0.61 ± 1.4	0	0.52 ± 1.7	0	–	0.631
One month after 1st dose	21.6 ± 63	22.4% (19)	5.08 ± 29.8	4.7% (4)	–	<0.001
Two months after 1st dose	65.6 ± 90.6	60.7% (51)	31.03 ± 60.3	44% (37)	–	0.038
Six months after 1st dose	115.7 ± 109.9	73.8% (62)	133.1 ± 106.25	88.2% (67)	–	0.018
Eight months after 1st dose	141.24 ± 110.15	78.8% (67)	194.3 ± 91.73	93.4% (71 out of 76 subjects who completed vaccination series)	–	0.002

‡ At the end of each vaccination protocol, compliance was 100% in group A and 90.4% in the classic vaccination schedule (group C). Data are reported using analysis of per protocol population.
* Seroprotection rates at each time point is calculated according to the number of those vaccinated and available for follow-ups. Data were compared using Pearson Chi-Square test and P value of less than 0.05 is considered significant.
** Seroprotection is defined as anti HBs-Ab titers of >10 IU/L.

Two months after first vaccine dose, seroprotection was achieved in 60.7% of individuals in group A who received HBV vaccine at 0, 1, 4 and 8 weeks while in group C 44% of individuals were seroprotected which was significantly lower than group A ($P=0.038$).

However at the study end point (8th month) and after analysis of per protocol population, rate of seroprotection was significantly higher in classic vaccination regimen compared to seroprotection rate in group A (93.4% vs. 78.8%, $P<0.002$).

However at the same time point, analysis of outcomes based on "intention-to-treat" population revealed different results considering that 76 out of the initial 84 participants in group C received full dose vaccination and were available for follow-up at this time point. This analysis is in fact what we defined as the success rate of vaccination protocols.

The detailed information regarding the seroprotection rate at different time points in each group is shown in Table 2 and Fig. 2.

3.3. HBs-antibody titer

Fig. 3 demonstrates the trend of changes in antibody titer during the implementation of vaccination protocols in both groups. It should be mentioned that the blood samples in the 1st month were collected one week after group A and C individuals had received their 3rd and 2nd vaccine doses respectively.

The mean anti-HBs titer was significantly higher in group A individuals compared to group C one month after implementation of vaccination schedules. However the antibody titer increased at a higher pace in group C after 6 months. The overall increase in antibody titers was significant at different time points ($P<0.001$).

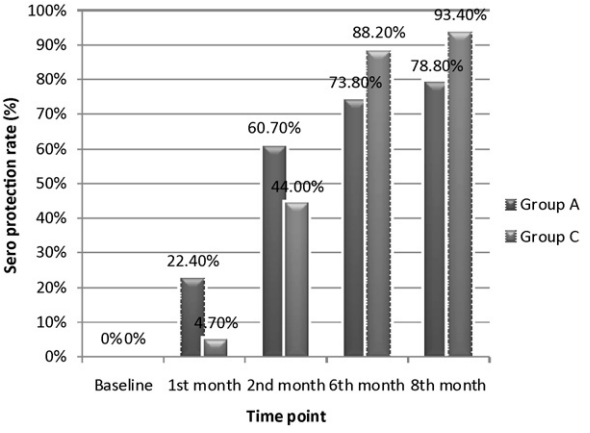

Fig. 2. Comparison of seroprotection rates in two vaccination groups during a period of 8 months after the first vaccine dose. Group A: accelerated HBV vaccination at 0, 1, 4 and 8 weeks; group C: classic HBV vaccination at 0, 1 and 6 months. Antibody titer of 10 IU/L and more is considered seroprotective.

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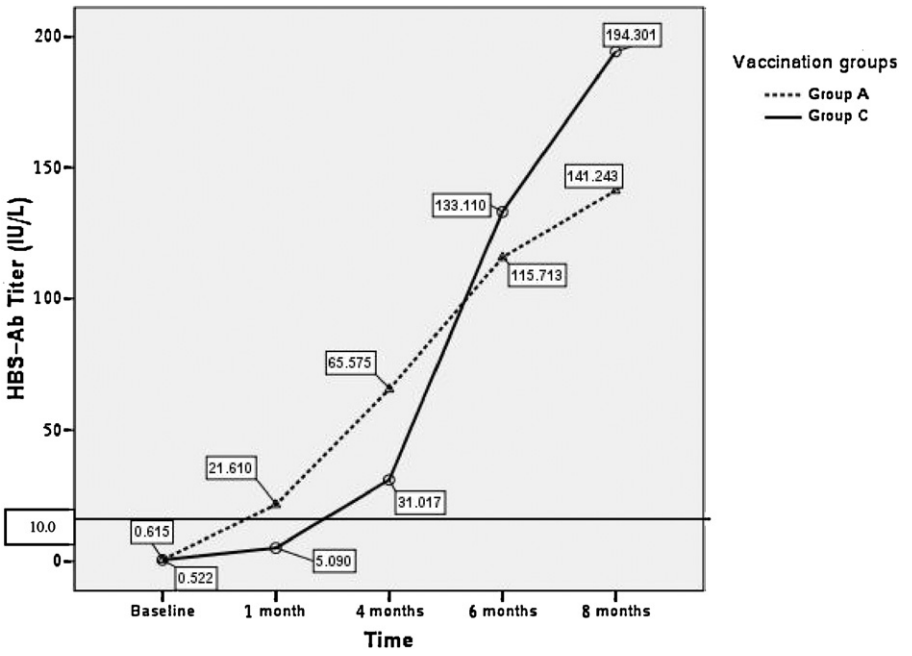

Fig. 3. Comparison of changes in mean antibody titer between three vaccination schedules during a period of 8 months after the first vaccine dose. Group A: accelerated HBV vaccination at 0, 1, 4 and 8 weeks; group C: classic HBV vaccination at 0, 1 and 6 months. Antibody titer of 10 IU/L and more is considered seroprotective. A significant increase in antibody titer at one month after vaccination is observed in group A while at the 8th month mean antibody titer in group C is significantly higher than group A. (Data were analyzed using repeated measures with $P < 0.05$ considered statistically significant.)

3.4. Success rate

None of the patients developed signs of new HBV infection during the trial. Fig. 4 demonstrates the success rate of vaccination among the two vaccination groups. Comparison of success rates between group A and group C individuals revealed that although higher seroprotection rate was achieved in group C individuals but the overall success rate in both groups did not differ significantly (analysis of the intention-to-treat population) (78.8% vs. 84.6%, $P = 0.466$).

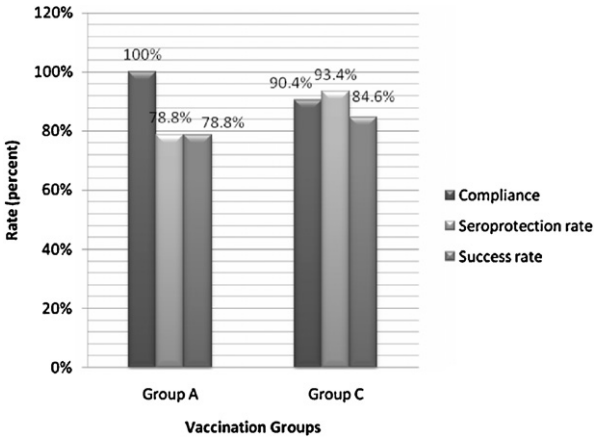

Fig. 4. Comparison of overall outcome of three vaccination protocols at 8 months after the first vaccine dose. Group A: accelerated HBV vaccination at 0, 1, 4 and 8 weeks; group C: classic HBV vaccination at 0, 1 and 6 months. *Success rate was defined as the proportion of individuals who received the full dose of vaccination and were seroprotected based on the total number of participants in each group (success rate had no significant difference among group A and C individuals ($P = 0.466$, Pearson Chi-square test). Compliance was significantly higher in group A ($P < 0.001$). Seroprotection was significantly higher in group C at this time point ($P = 0.002$, Pearson Chi-square test).

4. Discussion

HBV infection and its related complications such as cirrhosis or HCC can all be easily prevented by either form of HBV vaccines and their effectiveness have been established in several trials [21].

Although HBV vaccination resulted in a significant worldwide decline in HBV incidence in children and adolescents with high safety and cost-effectiveness, yet it has not been utilized sufficiently in adults especially in high risk groups and therefore these groups remain susceptible to HBV related complications [22,23].

Incarceration and injection are among risk factors for development of viral hepatitis B. An investigation in England revealed that more than 70% of injecting drug users (IDUs) has history of incarceration. Furthermore anti-HBc was tested positive in 8% of prisoners and in 21% of IDUs [24,25]. This implies the need for a more appropriate strategy toward vaccination of this high risk group against HBV. However one main obstacle in proper vaccination of prisoners is the long duration of classic HBV vaccination schedule (6 months). Additionally it is shown that in prisons, IDUs while being at higher risk for HBV infection spend less time in jails than others in an episode of imprisonment which further restricts proper full dose vaccination [26].

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The current trial tested two rapid HBV vaccination regimens regarding their efficacy compared with the classic 0, 1 and 6 months vaccination schedule.

Although overall classic HBV vaccination protocol provided statistically higher rates of seroprotection in inmates, however immunity that was achieved in the accelerated group could be considered clinically significant. Our investigation revealed higher seroprotection rate at the primary endpoint of this trial in those receiving classic 6 month HBV vaccination but in one month after the first vaccine dose, the accelerated group achieved significantly higher seroprotection rate. At the study endpoint, seroprotection rate in groups A and C individuals were 78.8% and 93.4% respectively.

A standard for an effective HBV vaccination program is considered to be the one that accomplishes at least 85% seroprotection in target groups [20,27]. However due to prisoners' lower compliance, a vaccination schedule that can achieve at least 75% of seroprotection is considered an ideal regimen for implementation in prison setting [20,27]. Therefore the clinically significant 78.8% protection rate that was achieved in this survey in accelerated 0, 1, 4 and 8 week schedule favors the efficacy and feasibility of such regimen in prisoners. Other investigations have also recommended such accelerated regimens over the classic vaccination since longer duration of vaccination is accompanied by less compliance in prisoners [28].

Up to our knowledge there are a few investigations that have evaluated the role of accelerated HBV vaccination on prisoners and several other reports have evaluated the success of such regimens on different target groups such as children, homeless or health care workers. The protocols used in such studies consisted of 3 doses at 0, 1 and 3 weeks or 3 doses at 0, 10 and 21 days which are different from our accelerated schedule (0, 1, 4 and 8 weeks) [29–31].

The most comparable proposed regimen to our accelerated schedule was the one suggesting vaccination at 0, 1 and 2 months with 20 μg recombinant HBV vaccine with a booster dose at 12 months [20].

Christensen et al. [32] performed a randomized and a nonrandomized trial of an accelerated (0, 1 and 3 weeks) HBV vaccination protocol in Danish and Estonian prisoners and reached a 67% of seroprotection at 7 months after first dose which is lower than seroprotection rate achieved in our accelerated (0, 1, 4 and 8 weeks) schedule at either 6 months (73.8%) or 8 months (78.8%) after first dose.

Joines et al. [33] demonstrated that HBV vaccination at 0, 7 and 21 days with a booster at 12 months results in 65% seroprotection rate in 8 weeks after first dose which is comparable to our results in the 0, 1, 4 and 8 weeks schedule group at the same time point (60.7%). However the rate of seroprotection was 99% at month 13, one month after the booster dose.

Application of a 3 dose (0, 10 and 21 days) HBV vaccination program resulted in 65% seroprotection rate one month after the first dose and 70% after 6 months in a survey in Turkey [34]. Although in our accelerated regimen lower seroprotection was achieved after one month (22.4%) compared to Bosnak et al. [34] study but after 6 months, the protection rate increased to 73.8% which is higher than what was achieved in their study.

Comparison of classic vaccination protocol with a 3 dose (0, 10 and 21 days) schedule in another investigation in Turkey revealed similar seroprotection rates in both groups in contrast to our findings [35].

Furthermore and similar to our findings, the mean titer of antibody against HBsAg was significantly higher in the classic vaccination group compared to the accelerated group.

It is worth mentioning that effectiveness and suitability of a vaccination protocol is not entirely attributed to the rate of seroprotection it can accomplish in the target population especially in high risk groups such as prisoners. Compliance of individuals to receive full dose vaccination is another important factor. Therefore both seroprotection rate and compliance of individuals should be taken into account to evaluate the efficacy. Therefore we defined "success rate" to more accurately evaluate success of a vaccination program which is actually the "intention to treat" analysis of seroprotection rate in each group.

Although eventually higher seroprotection rate was noted in group C individuals but comparison of success rates revealed no significant difference between the two groups. (78.8% in group A compared to 84.6% in group C.)

As demonstrated in Fig. 3, anti-HBs titer in subjects in accelerated vaccination group, increased and reached seroprotective levels more rapidly compared to classic vaccination group ($P < 0.001$). Although in group C, antibody titers started to increase at higher pace after 6 months but considering the necessity of rapid immunization of high risk individuals in this setting, accelerated protocol was in fact more successful in providing early seroprotection.

There were also several limitations to our investigation the most important of which was our relatively small sample size in this trial. This could have impacted the analysis and restricted our interpretation of the results as an evidence for future practice. Additionally this investigation was only carried out on male prisoners whereas female inmates should have also been included. This was due to several legal issues which led to us not be able to obtain the approval for participation of female prisoners.

In conclusion, classic vaccination program seems to be more efficient in terms of seroprotection rate. However, considering the relatively lower compliance in classic vaccination group on one hand (especially for the third vaccine dose) and the earlier seroprotection achieved in the accelerated 0, 1, 4 and 8 week regimen on the other, the accelerated protocol can be suggested for prisoners with shorter sentences (especially less than 6 months) with acceptable effectiveness and success.

There might be concerns on whether administering a 4 dose accelerated vaccination schedule compared to the classic three dose protocol is cost beneficial in prison settings. Considering the allocated financial resources for prevention of HBV infection by Iran's Ministry of Health which also includes vaccination of prisoners, there seems to be little financial issues on providing HBV vaccine in prisons. However, more investigations are needed to eval-

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uate the cost-effectiveness of such protocols compared to classic regimens especially in long-term, considering the resources that might be saved in long-term by immunizing more high-risk individuals against HBV infection.

Implementation of an accelerated 0, 1, 4 and 8 weeks HBV vaccination protocol results in acceptable compliance and seroprotection which is beneficial in high risk groups such as injecting drug users and prisoners in which rapid immunization is warranted.

The benefits of these accelerated vaccination programs is not limited to IDUs or prisoners. It can also be an effective rapid method for induction of immunity in other high-risk groups such as children traveling to endemic areas, homeless or those who need transfusion of blood products as soon as possible.

However further evaluation of accelerated schedules regarding efficacy in longer follow-ups can provide more clues toward the benefits of such regimens.

Conflict of interests

The authors hereby disclose any conflict of interests.

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