General Principles of Vaccination of Pediatric Candidates of Kidney Transplant in Iran

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Pediatric organ transplantation, specifically kidney transplant, has improved considerably in recent decades in Iran. Since infections are the most common cause of morbidity and mortality among transplanted children, pre-transplant vaccination is an effective preventive tool in this regard. In addition, administration of some vaccines is contraindicated in post- transplant period and the efficacy and immunogenicity of authorized vaccines may also be suboptimal in comparison to normal population. Therefore, pre-transplant period offers an outstanding chance to boost the immunization of this population. With regard to this population, it is imperative to establish a localized vaccination guideline, which can be used by nephrologists and other clinicians who are part of the transplant team, in Iran. Currently, such a local guideline for Iranian pediatric kidney transplant candidates is not available. The aim of this study is to provide a comprehensive overview of the existing vaccines recommended for these cases regarding the Expanded Program on Immunization (EPI) and available vaccines in Iran. In addition, general principles of vaccination, the use of specific vaccines as well as accelerated vaccination in this population are discussed in this article. This review could be a preliminary guide for preparing a comprehensive guideline for vaccination of this population in Iran.

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INTRODUCTION

Children and adolescents with chronic kidney disease should receive all essential vaccines as soon as possible and early in their illness preferably before progression of renal failure according to their age and health status. [1] Ideally, children who are candidates of kidney transplant should receive as many essential vaccines as possible before transplantation as well.[2]

There are some local and universal guidelines for vaccination of candidates of solid organ transplantation in adults and pediatric field. Since the expanded program of immunization of Iran is not exactly the same as the vaccination schedule of other countries, it seems that a local guideline is required for the pediatric nephrologists and other clinicians who are part of the transplant team. Presently, such a localized guideline for pediatric candidates of kidney transplant in Iran is not available. In addition, there are some vaccines, which are recommended for this population, but are not included in the expanded program of immunization of Iran. Therefore, we tried to provide a preliminary guide for preparing a comprehensive vaccination program for this population.

SEARCH METODS

We searched the following databases and

resources from 2000 until the end of 2022: PubMed, Cochrane Library, Google Scholar and UpToDate. We used Mesh terms in English language. We also searched the last edition of Red book and Schedule and Guideline of Immunization published by National Immunization Technical Advisory Group of the Ministry of Health and Medical Education of Iran.

GENERAL POINTS

It should be mentioned that the immune response to many vaccines decreases in the advanced renal failure and also in the post-transplant period. In addition, the live vaccines are generally contraindicated in the post- transplant period .[3]

While kidney transplant candidates, compared to the general population, may not obtain the optimum immunity, their responses are comparatively better than those of post-transplanted individuals.[4] Therefore, the pre-transplant period presents a valuable opportunity to enhance the the immunity status of this specific population.[4]

Vaccination status should be checked in the first visit of the patient. An individualized vaccination schedule should be established and evaluation of secondary serological responses to vaccine administration be performed, if necessary. In addition, the vaccination status should be re-evaluated when the patient is included in the transplant list.[3] Kidney transplant candidates should receive inactivated vaccines at least two weeks and live vaccines four weeks before transplantation.[5]

The immune response to the vaccines and safety of live ones may be affected by using the immunosuppressive drugs such as rituximab before transplantation. It is suggested that vaccination be postponed for at least 6 months after rituximab to ensure that inactivated vaccines are effective and live vaccines are safe.[4]

In addition, the renal transplant candidates may need to use some immunosuppressive medications such as azathioprine, cyclosporine, and cyclophosphamide. Although the proper time interval between the discontinuation of immunosuppressive medication and safe live vaccine administration is unknown, a period of at least three months is required for the immune system to be recovered and the safe administration of live vaccines to be achieved.[4] However, many individuals, on immunosuppressive therapy, are unable to discontinue their treatment in order to be immunized.[4]

If vaccination has been started before transplantation but not completed, depending on the type of vaccine, it might be continued and completed in the post-transplant period if there is no contraindication.[1,3]

Most transplant centers resume immunization protocols approximately 3 to 6 months after transplantation, when immunosuppression has reached maintenance level. Nevertheless, the administration of the influenza vaccine is feasible one month after transplantation.[3]

It is noticeable that vaccination should be avoided during active phase of transplant rejection.[3]

Although the immunization status of living kidney donors should also be updated, donor vaccination is not advised only for recipient benefits.[6] Donors should stop receiving the live vaccines at least four weeks prior to donation. Siblings and family members of kidney transplant recipients should be vaccinated according to the national vaccination program (NIP).[6] Vaccination status of family members of transplant recipients should also be checked.[5]

LIVE VACCINES

Administration of live vaccines after transplantation is relatively contraindicated due to concomitant administration of immunosuppressive medications. This point emphasizes the importance of immunization of susceptible children soon before transplantation. To reduce the risk of vaccine-related infections in the post-transplant period, it is generally recommended that live virus vaccines be administered to children aged 9 to 12 months and up to 1 month before transplantation.[1]

Among live vaccines, measles, mumps and rubella (MMR), oral polio (OPV), and Bacille Calmette-Guerin (BCG) vaccines are included in the expanded program of immunization of Iran.[7] Currently varicella, and rotavirus vaccines, are not routinely administered in Iran but are recommended for candidates of pediatric kidney transplant.[3] In the next section, some live vaccines are discussed.

Varicella Vaccine

Currently, the varicella vaccine is not included in Iran's NIP.[7] All kidney transplant candidates are recommended to be screened for anti-varicella

IgG antibodies during pre-transplant evaluation and vaccinated if eligible and unimmunized.[3]

Individuals aged 1 to 12 years should receive two doses of the varicella vaccine with a minimum interval of three months between doses; those aged 13 and older should receive two doses with a minimum interval of four weeks.[9]

The presence of antibodies against Varicella Zoster Virus (VZV) in infants less than 12 months of age may still be secondary to maternal (placental-transmitted) antibodies; therefore, it may be assumed that children under one year of age are not immune and could be vaccinated without measuring anti VZV IgG level.[1]

Maternal antibodies against VZV can interfere with the response to the varicella vaccine, which is why the vaccine is most effective when the infant is at least one-year-old, and the maternal antibodies are diminished. However, the process of vaccination may be accelerated as a result of the timing of transplantation. In this regard, the varicella vaccine can be administered to pediatric kidney transplant candidates from the age of 6 months.[4] Two doses of vaccine can be administered with a minimum of four weeks between doses. Since the immune response at this age may be affected by maternal antibodies, if the varicella vaccines are given before the scheduled time, it should be repeated at 12 months of age if the kidney transplant has not yet taken place.[4]

MMR and varicella vaccines can be administered at the same time. Otherwise, the time interval between these two vaccines should be at least 28 days.[4]

The level of anti-varicella antibody should be checked four weeks after the second dose of vaccine. If there is enough time and the seroconversion has not occurred, an additional dose can be administered.[8]

Measles, Mumps, and Rubella (MMR) Vaccine

Infants less than 12 months of age often have maternally transmitted measles antibodies that may reduce the immune response to the MMR vaccine. Therefore, MMR vaccine is not normally recommended before 12 months of age in healthy children; however, children waiting for kidney transplant may not be able to delay vaccination until the age of one year.[1]

MMR vaccine can be administered from six months of age for those who are candidates of kidney transplant and need accelerated vaccination. The second dose of MMR can be given as soon as four weeks after the first dose of MMR vaccine.[1]The MMR vaccine should be given again to infants who are one-year-old, are candidates for a kidney transplant, have not yet transplanted and are not going to be transplanted in the next four weeks.[3]

In addition, Children who have not yet been vaccinated should receive the MMR vaccine as soon as possible (i.e., two doses, four weeks apart) .[5]

Checking antibody titers after immunization and prior to transplantation is recommended.[8]

Oral Polio Vaccine

Regarding the EPI of Iran, oral polio vaccine is administered in 6 doses (at birth, 2, 4, 6, 18 months and 4 to 6 years of age).[7] In addition, oral and inactivated polio vaccines (OPV, IPV) are used simultaneously at four and six months of age. OPV administration is contraindicated in immunocompromised children and their household contacts.[1,2] In the countries where both OPV and IPV are available, IPV is the vaccine of choice for kidney transplant candidates and people in their close contacts.[1] It is recommended to use non-live polio vaccine for children who are candidates of kidney transplant.[1]

The renal transplant candidate who has not been fully vaccinated with OPV or IPV should receive the remaining doses with IPV regardless of the time between the last dose and the type of vaccine that the candidate has already received.[1]

Rotavirus Vaccine

Currently, this vaccine is not included in the EPI of Iran[7] but five rotavirus vaccines are available in the world. RotaTeq is a live oral pentavalent rotavirus vaccine that is administered as a 3-dose series (2, 4, and 6 months of age).[9] Rotarix is a live, attenuated oral monovalent rotavirus vaccine, given as a 2-dose series (2 and 4 months of age).[9] Minimum age for the first dose and maximum age for the last dose of these rotavirus vaccines are 14 weeks, and 8 months of age, respectively.[9]

Rotavac, a monovalent and Rotasill, a pentavalent vaccine are two live oral rotavirus vaccines which are administered as a 3-dose oral regimen, four weeks apart, beginning at six weeks of age.[9] Rotavin-M1 is a monovalent rotavirus vaccine

administered orally in a two-dose schedule, with the first dose at six weeks and the second dose 2 months after the first dose.[9] Rotavirus vaccines are recommended for pediatric candidates of kidney transplant in an age-appropriate schedule.[4]

Bacillus Calmette-guerin (BCG) Vaccine

BCG vaccine is a live vaccine containing attenuated strains of *Mycobacterium bovis* (*M. bovis*).[7] Since the BCG vaccine is administered at birth in Iran,[7] children who are candidates for kidney transplant have usually received the vaccine. However, BCG vaccine should not be prescribed to immunodeficient patients.[2]

NON-LIVE VACCINE

Among non-live vaccines, diphtheria, tetanus, pertussis, haemophilus influenza type B, Inactivated polio and hepatitis B vaccines are included in the EPI of Iran. Presently, hepatitis A, and human papillomavirus (HPV) vaccines are not included in the Iranian national immunization program (NIP).[7] Hepatitis A vaccine is recommended in special situations but HPV vaccine is recommended for all eligible candidates of kidney transplant.[1,3] In the next section, some non-live vaccines are discussed.

Diphtheria and Tetanus Vaccine

In the current NIP of Iran, diphtheria and tetanus vaccines are administered in the form of a pentavalent vaccine (including diphtheria, tetanus, pertussis, haemophilus influenza B and hepatitis B vaccines) and trivalent vaccine (including diphtheria, tetanus, and pertussis vaccines).[7] Pentavalent vaccine is routinely administered at two, four, and six months of age. Two bivalent vaccines of diphtheria and tetanus (DT) for under 7 years old and Td for 7 years of age and older are also available.[7] If the vaccine administration needs to be accelerated, it can be started at 6 weeks of age and the dose interval can be reduced to one month.[1]

If the child has not completed the initial series at the time of the primary assessment, the program should be expedited.[1] Booster doses of diphtheria and tetanus vaccine should be administered every 10 years for both transplant candidates and recipients. [1]

Pertussis Vaccine

Currently, the type of pertussis vaccine used in Iran is the whole cell vaccine and is administered in the form of a pentavalent vaccine and is not recommended after 7 years of age.[7]

The series of pentavalent vaccine can be accelerated in pediatric renal transplant candidates (Table 1). Other siblings and close contacts who have not been fully vaccinated must complete their immunization schedule according to the national immunization schedule of Iran.[1,7]

Haemophilus Influenza Type B (HiB)

Regarding the NIP of Iran, this vaccine is currently administered as a part of the pentavalent vaccine at two, four, and six months of age.[7] If necessary, the HiB vaccine can be administered to pediatric transplant candidates according to an accelerated schedule. If the HiB vaccination is incomplete at the time of transplantation, it can be completed after transplantation, although the effectiveness of immunization has not been established.[1]

Hepatitis A Vaccine

The risk of hepatitis A infection is high in Iran. Therefore, people who are candidates for kidney transplant may be serologically positive. According to the NIP of Iran, this vaccine is not routinely administered to children.[7]

In contrast to liver transplant candidates, the hepatitis A vaccine is typically not recommended for kidney transplant candidates unless they are at risk for hepatitis A regardless of transplant risks[1], such as:

- living in communities with a high prevalence of hepatitis A
- homosexuality
- history of drug abuse
- clotting-factor disorders
- occupational exposures

Due to the high prevalence of this disease in Iran, a child who is a candidate for the kidney transplant should undergo a serological examination and, if diagnosed not immune, receive the hepatitis A vaccine.[10] In accelerated vaccination program, hepatitis A virus (HAV) vaccine can be administered in two doses from six months of age with an interval of four weeks.[1] Evaluation of the serological response after immunization is recommended and serologically negative patients should be revaccinated.[1]

Table 1. Accelerated Vaccine Schedule of Pediatric Kidney Transplant Candidates of Iran

Vaccine	Check and update the vaccination status of household contacts	Determination of serologic status	Minimum intervals between vaccine doses	Minimum age to receive the vaccine	Recommended after transplantation
Trivalent (diphtheria, tetanus, and pertussis)	Yes	Not routinely recommended	One and two 4 wks Two and three 4 wks Three and four 6 months Four and five 6 months	6wks	Yes
Pentavalent (diphtheria, tetanus, pertussis, Haemophilus influenzae B, and hepatitis B)	Yes	Not routinely recommended	One and two 4 wks Two and three 4 wks	6wks	Yes
Hepatitis B	Yes	Pre and post-transplant	One and two 4 wks Two and three 8 wks	At birth	Yes
Hepatitis A	No	Not routinely recommended unless with a new or continues risk	< one year one and two 4 weeks >one year, one and two 6 months	6 months	Yes
Haemophilus influenza type B conjugate vaccine	No	Not routinely recommended	One and two 4 wks Two and three 4 wks Three and four 8ws	6ws	Yes
Inactive influenza	Yes	Not routinely recommended	One and two 4 wks	6months	Yes
Meningococcal polysaccharide vaccine	No	Not routinely recommended		2years	Yes
Men ACWY conjugate (menveo)	No	Not routinely recommended	One and two 8 wks Two and three 8 wks Three and four 6 months	2 months	Yes
Men ACWY conjugate (menectra)	No	Not routinely recommended	One and two 3 months	9 months	Yes
Measles Mumps Rubella (MMR)	Yes	Pre and post-transplant	One and two 4 wks	6 months	No
BCG	No	Not routinely recommended		At birth	No
S. pneumoniae (13 valent conjugate vaccine)	No	Not routinely recommended	One and two 4 wks Two and three 4 wks Three and four 8 wks	6ws	Yes
S. pneumoniae (23valent polysaccharide Vaccine)	No	Not routinely recommended	One and two 5 yrs	2 years	Yes
Varicella vaccine	Yes	Pre and post-transplant	One and two 4 wks	6 months	No
Human papilloma virus vaccine (HPV)	No	Not routinely recommended	One and two 4 wks Third dose 24 wks after the first dose	9 years (from 7 years can be considered)	Yes
Rotavirus Vaccine (RotaTeq)	No	Not routinely recommended	One and two 4 wks Two and three 4 wks	6 wks	No
Rotavirus Vaccine (Rotarix)	No	Not routinely recommended	One and two 4 wks	6 wks	No

If the transplantation is postponed to one year of age or later, in case of using Harvix vaccine, two doses are administered at intervals of six to 12 months from one year through 18 years of age. In case of Vaqta type, two doses are prescribed at intervals of six to 18 months.[8,10]

Hepatitis B Vaccine

At present, the coverage of immunization of neonates and infants with the recombinant hepatitis B vaccine is high and is estimated to be more than 95% in Iran. [11] Therefore, many children have received the full series of this vaccine and are completely immunized when pre-transplant evaluation is performed.

However, some children have not received the full course of their HBV vaccine, or have an underlying disease that directly or indirectly reduces the immune response to the vaccine, or rarely have no history of HBV immunization. [1]

Recombinant hepatitis B is highly immunogenic in healthy children. Vaccine efficacy is directly related to the antibody titer.[1] Individuals with titers ≥ 10 milli-international units per milli liter (mIU/mL) are approximately 100% protected against clinical disease and chronic infection caused by hepatitis B virus (HBV).[1]

Candidates of kidney transplant with negative hepatitis B surface antigen (HBs Ag) and hepatitis B surface antibody (HBs Ab) titer < 10 mIU/mL must receive hepatitis B vaccine, followed by checking Hbs Ab titer.[5]

All pediatric kidney transplant candidates should be serologically tested for immunity against hepatitis B infection. Candidates who are not immune and have not received complete hepatitis B vaccination series should complete the vaccination expeditiously [≤ 10 years 0.5 mL, > 10 years 1 mL, adults on dialysis two mL (double dose)].[7]

The vaccination should be repeated if patients have not achieved the protective levels of antibodies after this series by re-administering a full series of three doses of vaccine or a single dose and testing for HBs Ab titer.[1] Hepatitis B surface antibody titer should be monitored four weeks after the last dose of vaccine administration to record the protective titer.[1]

Inactivated Polio Vaccine (IPV)

Children undergoing kidney transplantation should speed up their vaccination schedule.[1] The vaccination status of their household contacts should also be checked.[1] Candidates and household contacts who have not received the recommended doses of IPV or OPV should receive adequate doses of IPV and the administration of vaccine series can be continued with the next recommended dose of IPV regardless of the type of vaccine already received.[1,2] If the immunization series cannot be completed before transplantation, IPV is safe after transplantation, but its immunogenicity is less likely to be adequate after transplantation.[1]

Human Papillomavirus Vaccine (HPV)

Transplant recipients are at higher risk for HPV-related malignancies than healthy people.[3,4] The HPV vaccine is a non-live vaccine and is recommended for girls and boys who are candidates for kidney transplant from the age of nine years. However, in the accelerated immunization, vaccination from 7 years of age could be considered.[6] The vaccine should be given in three doses before transplantation.[12] Currently, three types of the HPV vaccine are available in the world: the bivalent, quadrivalent and the 9-valent vaccines.[13]

Presently, the 9-valent HPV vaccine (Gardasil 9) licensed by the FDA in 2014[13]is not routinely available in Iran. Therefore, a quadrivalent or if not available bivalent vaccine (Gardasil)[13] is recommended. It is administered at intervals of 0, 1 to 2 (minimum interval of four weeks) and six months (minimum interval of five months after first dose) and preferably before transplantation. If the vaccination is incomplete before transplantation, additional doses can be started 3 to 6 months after transplantation [3,12]. It must be noticed that in kidney transplant candidates and recipients the number of doses recommended are always three, even if administered before 15 years of age.[13]

Influenza Vaccine

Annual influenza vaccine administration is recommended for all patients with CKD and renal transplant candidates and those in contact with them.[1,4]

Tetravalent inactivated influenza vaccines are available in Iran and renal transplant candidates and CKD cases should receive the inactivated influenza vaccine from six months of age.[1,7]

However, the antibody response in CKD and

kidney transplant candidates may not be as strong as in healthy children.[1]

The influenza vaccine should be given to all kidney transplant candidates and their household contacts before the start of influenza season, preferably by the end of October, or at the time specified in the annual recommendations of the Advisory Committee on Immunization Practices (ACIP) each year.[14]

If the candidate is six months through eight years of age and has never received the influenza vaccine, he or she should receive two doses of the vaccine four weeks apart for the first time of administration, followed by one dose annually.[14]

For people less than nine years of age who have already received the influenza vaccine and cases of nine years of age or older, annual administration of a single dose of the vaccine is sufficient.[14]

Pneumococcal Vaccine

In Iran, pneumococcal vaccine is not yet included in the NIP.[7] Two vaccines are currently licensed for use in pediatric kidney transplant candidates; the 23-valent polysaccharide vaccine (PPV23) which is not immunogenic at the age of less than 2 years and is administered after two years of age and the 13-valent conjugate polysaccharide vaccine (PCV13), which can be administered in children under two years of age.[3]

Pediatric candidates of kidney transplant should receive a course of PCV13, followed by a dose of PPV23 two months after receiving the last dose of PCV13 vaccine when the child is at least two years old.[3]Antibody concentrations decrease rapidly following PPV23, and revaccination is recommended for candidates of kidney transplant five years after initial vaccination (Table 2).[15]

Meningococcal Vaccine

It is not exactly known whether renal transplant recipients are at increased risk for meningococcal disease. However, the tetravalent conjugated meningococcal vaccine is recommended for renal transplant candidates with a risk factor for invasive meningococcal infection (such as asplenia, and eculizumab treatment).[8] According to, according to the consensus statement from the Pediatric Group of the Canadian Society of Transplantation, solid organ transplant candidates are considered high risk due to impending immunosuppression and should be vaccinated against meningococcal disease.[6]

The meningococcal polysaccharide vaccine (MPV) is relatively ineffective in children under two years old. Antibody concentration declines rapidly following MPV administration, and revaccination is recommended for candidates and recipients of kidney transplant 3 to 5 years after initial vaccination.[1]

Three types of tetravalent meningococcal conjugate vaccines, Menveo, Menactra and Nimenrix. are available in Iran and are immunogenic in cases of children less than two years of age. The Menveo vaccine is administered in 4 doses at 2, 4, 6, and 12 months of age. The Menactra vaccine is administered in two doses at 9 and 12 months of age.[16] Nimenrix can be used as soon as 6 weeks of age. For patients from 6 weeks to less than 6 months of age, two doses of Nimenrix vaccine on 2 and 4 months of age and the booster dose at 12 months (at least 2months after the last dose) is recommended. Infants from 6 months of age, children, adolescents and adults need only one dose of this vaccine.[16]

It should be noted that the need for this vaccine

Table 2. Pneumococcal Vaccination Schedule of Renal Transplant Candidates After 24 Months of Age

Previous dose	Recommendations
24 to 71 months	
Unvaccinated or less than 3 doses of PCV13 before 24 months of age	Two doses of PCV13, The first dose 8 weeks after the previous dose. 1 dose of PPSV23, 8weeks after the last dose of PCV13
3 doses of PCV13 before 24 months of age	One dose of PCV13, 8weeks after the previous dose of PCV13 1 dose of PPSV23, 8 weeks after the last dose of PCV13
6 to 18 years	
No previous dose of PCV13 or PPSV23	1 dose PCV13, First dose of PPSV23 8 weeks after PCV13and the second dose of PPSV23 5 years after the first dose of PPSV23
1 dose PCV13	1 dose of PPSV23 8 weeks after PCV13 and the second dose of PPSV23 5 years after the first dose of PPSV23
1 dose of PPSV23 without previous dose of PCV13	1 dose of PCV13 8 weeks after the previous dose of PPSV23 A second dose of PPSV23 5 years after the first dose of PPSV23.

in pediatric candidates of kidney transplant should be determined with more studies in the future and a universal consensus remains to be defined.[1]

COVID-19 VACCINES

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) emerged at the end of 2019 with limited treatment options. Vaccination strategies are considered as a significant way to prevent severe COVID-19.[17] Currently, there are two vaccines approved by the CDC, Pfizer and Moderna COVID-19 vaccines for use in eligible children and adolescents aged six months and older.[18] Sinopharm BBIBP-CorV and SOBERANA 02 known as PastoCovac are two vaccines that have been approved and recommended by Ministry of health of Iran for use in eligible children of five years and older in Iran.[20]

Sinopharm BBIBP-CorV is an aluminum-hydroxide-adjuvanted, inactivated whole-virus vaccine while SOBERANA 02 is a COVID-19 conjugate vaccine [recombinant receptor-binding domain (RBD) conjugated to tetanus toxoid].[19] These two vaccines are administered in two doses with interval of 28 days. An additional dose as a part of primary series of vaccine is recommended in cases of immunocompromised and high-risk groups including CKD and renal transplant candidates of 12 years and older.[20]

It should be noted that immunocompromised individuals may still be at increased risk of COVID-19 despite vaccination, Therefore, infection preventive measures such as wearing a mask, avoiding crowds and poorly ventilated indoor spaces and physical distancing should be continued.[18]

FURUTE PERSPECTIVE IN VACCINATION OF PEDIATRIC CANDIDATES OF KIDNEY TRANSPLANT IN IRAN

It is suggested to conduct studies to determine if the pediatric candidates of kidney transplant are more susceptible to meningococcal infection in comparison to normal population. In addition, the recent studies have revealed that the prevalence of HAV infection has changed and the age of this infection has increased in Iran. Therefore, it is suggested to evaluate if it is necessary to consider hepatitis A vaccine in the schedule of this population.

AUTHORSHIP CONTRIBUTIONS

Shirin Sayyahfar designed the study; wrote the first draft and is the guarantor. Masoumeh Mohkam contributed to design of the study, writing the first draft, and revised the final manuscript. Nakysa Hooman revised the final manuscript. Foroozan Faress contributed to database searching, and finalized the manuscript.

CONFLICTS OF INTEREST

The authors declare no conflict of interest.

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