Clinical Trial | J Adv Med Biomed Res. 2025; 33(157): 164-171

Category: Clinical Medicine | Peer Reviewed | Open Access

Journal of Advances in Medical and Biomedical Research | ISSN:2676-6264

The Effect of Vitamin A and Corticosteroid in Reducing Kidney Scars in Children with Acute Pyelonephritis: A Clinical Trial Study

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Article Info

10.30699/jambr.33.157.164

Received: 2025/01/28;
Accepted: 2025/05/01;
Published Online: 29 May 2025;

Use your device to scan and read the article online

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ABSTRACT

Background & Objective: To investigate the effect of vitamin A and Corticosteroid in reducing kidney scars in children with acute Pyelonephritis (PN).

Materials & Methods: This clinical trial study was conducted on 45 children with acute pyelonephritis. Patients were randomly divided into three groups of vitamin A (n= 15), Corticosteroid (n= 15) and placebo (n= 15). In addition to standard treatment for all patients, the first group received vitamin A once a day and each time 25,000 units for children under one year and 50,000 units for children one year and older during 3 days of hospitalization intravenously. The second group received Corticosteroid (dexamethasone) daily 0.15 mg/kg/day in two divided doses (25) during three days of hospitalization intravenously. The placebo group received normal saline as an injection. All patients were followed up for 6 months.

Results: The recovery rate of abnormal lesions in the vitamin A, Corticosteroid and placebo groups was 46.7%, 6.7% and 26.7% respectively, and this difference was statistically significant (P-Value=0.016). Also, the results of 99mTc-dimercaptosuccinic acid (DMSA) before and after intervention was statistically significant only for the group receiving vitamin A, so that 46.7% of the total 66.7% patients with abnormal lesions in the first 99mTc-DMSA scan had improved after the intervention in the the second 99mTc-DMSA scan (P-Value =0.001).

Conclusion: Vitamin A may be effective in reducing kidney scars in children with APN.

Keywords: Kidney Scar, Pyelonephritis, Corticosteroid, Vitamin A, Clinical Trial Study

1. Introduction

Urinary tract infection (UTI) is one of the most common infectious diseases in children, the prevalence of which is estimated at 1-3.5% and its most severe form is acute pyelonephritis, which is caused by invading pathogens. Escherichia coli is the most common cause with a prevalence of 80-90% (1, 2). Pyelonephritis (PN) induced by renal parenchymal infection is considered as a potentially life-threatening condition which leads to the renal scarring (3). Pyelonephritis is responsible for 0.7% of children's visits to the doctor's office and 5 to 14% of visits to the emergency department (4). Acute pyelonephritis (APN) is responsible for kidney failure in 8-20% of children and young adults (5). The symptoms of APN in the early stages are non-specific, however, delay in diagnosis and timely treatment can lead to the formation of irreversible kidney scars. Evidence suggests that 5-15% of first febrile UTIs in children can lead to kidney scarring (6, 7). The incidence of renal scarring following APN ranges from 5 to 57% and is associated with an increased risk of progressive renal damage. It can even lead to long-term cardiovascular complications and

chronic kidney failure in children (8). Therefore, to prevent complications such as irreversible scarring, high blood pressure, chronic kidney disease and sepsis, APN requires proper diagnosis and treatment, especially in children (9).

Antibiotics therapy is considered as the first therapeutic choice for acute pyelonephritis treatment to prevent the progression of disease (10). However, antibiotic administration alone may not be effective in preventing kidney scarring in children with APN (11). Considering inflammation and oxidative stress as potential underlying mechanisms of renal damage in APN, anti-inflammatory or antioxidant therapy given at the same time as antibiotics may reduce the risk of scarring after pyelonephritis (12). Blocking the inflammatory cascade involved in kidney scarring has been proposed as one of the treatment strategies. In addition, animal studies have shown that the use of Corticosteroid (dexamethasone), anti-inflammatory drugs (ibuprofen), dapsone, or melatonin/oxytocin can significantly reduce kidney scarring and its long-term consequences (13-15).

Currently, there are many antibiotic treatments for pyelonephritis, which in most cases require the patient to be hospitalized (sometimes for several days) and endure side effects of the drugs. Therefore, the aforementioned cases along with the high costs and the lack of sufficient facilities in hospitals have prompted researchers to look for new treatment methods to reduce the duration of hospitalization and reduce the complications caused by pyelonephritis (16, 17). Studies have suggested that among the vitamins, vitamin A, as a micronutrient supplement, may have an effect on the incidence of pyelonephritis. Also, immunodeficiency that can increase the risk of urinary tract infections following vitamin A deficiency has been reported (8, 18). Vitamin A as an anti-inflammatory substance includes retinol, retinal, retinoic acid and several provitamin a carotenoid (mostly beta-carotene). Considering the role of beta-carotene as an effective agent in deactivating free oxygen radicals and retinol as a hormonal growth factor for epithelial cells, vitamin A is expected to work effectively in restoring damaged mucosal surfaces (19, 20). On the other hand, it has been found that the severity of renal scarring is higher in people who have lower levels of vitamin A (21). However, due to the limitations of the studies conducted regarding the effect of vitamin A and other anti-inflammatory drugs along with standard treatment on kidney scarring in children with APN, this clinical trial study was designed to investigate the effect of vitamin A and Corticosteroid in reducing kidney scars in children with APN.

2. Materials and Methods

2.1 Study Design and Subjects

This clinical trial study was conducted on 45 children with acute pyelonephritis referred to pediatric nephrology clinic of Imam Reza Kermanshah hospital in 2022. Patients were randomly divided into three groups of vitamin A (n= 15), Corticosteroid (n= 15) and placebo (n= 15). The sampling method was convenience. The inclusion criteria were 1- age 3 months to 6 years 2- diagnosis of acute pyelonephritis 3- The positiveness of all urine cultures 4- hospitalization 5- consent to participate in the study. The exclusion criteria included 1- neurogenic bladder 2- obstructive uropathy 3- intolerance to vitamin A 4- occurrence of symptoms of vitamin A poisoning (including breath odor, hypotension, hypertension and apnea).

2.2 How to do the intervention

Diagnosis of acute pyelonephritis was made by a specialist physician. Then all patients were subjected to standard treatment so that during hospitalization, they were treated with ceftriaxone 75 mg/kg/day twice a day intravenously. Then, the treatment with oral Cefixime 8 mg/kg/day was continued until the end of 10 to 14 days after hospitalization at home. Then, eligible patients divided into three groups using permuted balanced block randomization (vitamin A, n=15; Cortone, n=15 and placebo, n=15). The first group, in addition to the standard treatment, received vitamin A once a day and each time 25,000 units for children under one year and 50,000 units for children one year and older during 3 days of hospitalization intravenously. The second group, in addition to the standard treatment, were treated with Corticosteroid (dexamethasone) daily 0.15 mg/kg/day in two divided doses during three days of hospitalization intravenously. For the third group, along with the standard treatment, normal saline was injected and were considered as the placebo group. Also, during the treatment, the children's parents were advised not to use ibuprofen at the same time due to its anti-inflammatory effects, as well as not to take the oral dose of vitamin A arbitrarily.

The data collection tool was a checklist including demographic variables, UTI symptoms, ultrasound findings, laboratory parameters, and first 99mTc-dimercaptosuccinic acid (DMSA) scan findings, which was collected for all patients before the intervention. In measuring the severity of hydronephrosis, hydronephrosis with grade 1 and 2 was considered as mild, grade 3 as moderate and grade 4 as severe hydronephrosis. After 6 months of follow-up, the second 99mTc-DMSA scan was repeated for the patients and the primary and secondary 99mTc-DMSA scans results were compared before and after the intervention.It should be noted that the results of two scans were evaluated for all patients by a nuclear medicine specialist.

2.3 Statistical Analysis

In descriptive analysis, mean (S.D) and number (%) were used for quantitative variables. In analytical analysis, the one-way ANOVA test and Chi square test to compare the quantitative ans qualitative variables in three group; respectively. The data were analyzed using SPSS26 software and P-Value <0.05 was considered as a significant level.

3. Results

This clinical trial study was conducted on 45 children with acute pyelonephritis referred to pediatric nephrology clinic of Imam Reza Kermanshah hospital. Patients were randomly divided into three groups of vitamin A (n= 15), Corticosteroid (n= 15) and placebo (n= 15). (Table 1 & 2) shows baseline variables, clinical symptoms and laboratory parameters before the intervention. The mean (±S.D) age were 30.80 (±24.41), 29.20 (±25.95) and 28.20 (19.02) days; respectively. The number (%) of girls were 11 (73.3), 11 (73.3) and 13 (86.7) in the three groups under study; respectively. In vitamin A, Corticosteroid and placebo groups 20, 26.7 and 33.3% had vomiting, respectively. Also, 13.3, 6.7 and 40% had diarrhea, respectively. The mean (±S.D) WBC were 14000 (±400), 14000 (±2800) and 12000 (3600); respectively. Generally, there were no significant statistical difference between the three groups groups in terms of baseline and clinical variables before intervention (P-Value>0.05). This lack of significant statistical difference between the two groups can be a reason that randomization process has occurred correctly. (Table 3) shows results of the first and second 99mTc-DMSA scans before and after intervention in the three groups under study. As can be seen, the results of the the first 99mTc-DMSA scan in the three groups did not have a statistically significant difference, which indicates the correctness of the random allocation process (P-Value>0.05). In addition, the results of the Chi square test showed the results of the second 99mTc-DMSA scan after the intervention were not statistically significant in the three groups (P-Value>0.05). However, after the intervention, the recovery rate of abnormal lesions in the vitamin A, Corticosteroid and placebo groups was 46.7%, 6.7% and 26.7% respectively, and this difference was statistically significant (P-Value=0.016).

(Table 4) shows the results of the first and second 99mTc-DMSA scans before and after intervention according to the three groups under study. As can be seen, the results of the comparison of the first and second 99mTc-DMSA scans were statistically significant for the group receiving vitamin A, so that 46.7% of the total 66.7% patients with abnormal lesions in the the first 99mTc-DMSA scan, recovery was observed in the the second 99mTc-DMSA scan (P-Value=0.001). However, the results of the comparison of the first and second 99mTc-DMSA scans was not significant for the Corticosteroid group, so that 33.3 % of the total 40% patients with abnormal lesions in the first 99mTc-DMSA scan, no change in recovery was observed in the second 99mTc-DMSA scan (P-Value =0.229).

Table 1. Comparison of baseline variables, clinical symptoms and laboratory parameters in three groups before the intervention

Qualitative Variables		Vitamin A	Cortone	Placebo	P-Value*
		Number (%)	Number (%)	Number (%)	
Sex	Boy	4 (26.7)	4 (26.7)	2 (13.3)	0.598
	Girl	11 (73.3)	11 (73.3)	13 (86.7)	
Residence	City	11 (73.3)	11 (73.3)	11 (73.3)	1.000
	Village	4 (26.7)	4 (26.7)	4 (26.7)	
Fever	Yes	14 (93.3)	15 (100)	15 (100)	0.360
	No	1 (6.7)	0 (0)	0 (0)	
Vomit	Yes	3 (20)	4 (26.7)	5 (33.3)	0.711
	No	12 (80)	11 (73.3)	10 (66.7)	
Diarrhea	Yes	2 (13.3)	1 (6.7)	6 (40)	0.054
	No	13 (86.7)	14 (93.3)	9 (60)	
Dysuria	Yes	10 (66.7)	12 (80)	13 (86.7)	0.407
	No	5 (33.3)	3 (20)	2 (13.3)	
Poor nutrition	Yes	6 (40)	4 (26.7)	4 (26.7)	0.661
	No	9 (60)	11 (73.3)	11 (73.3)	
Abdominal pain	Yes	8 (53.3)	5 (33.3)	5 (33.3)	0.435
	No	7 (46.7)	10 (66.7)	10 (66.7)	
CRP	+1	4 (30.8)	8 (57.1)	5 (38.5)	0.133
	+2	7 (53.8)	1 (7.1)	5 (38.5)	
	+3	2 (15.4)	5 (35.7)	3 (23.1)	
Nitrite	Positive	5 (33.3)	2 (13.3)	4 (28.6)	0.416

	Negative	10 (66.7)	13 (86.7)	10 (71.4)	
Pyuria	=<10	7 (50)	8 (57.1)	7 (46.7)	0.848
	>10	7 (50)	6 (42.9)	8 (53.3)	
Severity of hydronephrosis	None	10 (66.7)	11 (73.3)	10 (66.7)	0.815
	Low	4 (26.7)	3 (20)	5 (33.3)	
	Moderate	1(6.7)	1(6.7)	0 (0)	
	Severe	0 (0)	0 (0)	0 (0)	

*: Chi square test

Table 2. Comparison of baseline variables and laboratory parameters in three groups before the intervention

Variable	Groups	Number	Mean	S.D	P-Value*
Age (month)	Vitamin A	15	30.80	24.41	0.946
	Cortone	15	29.20	25.95	
	Placebo	15	28.20	19.02	
Height (cm)	Vitamin A	15	87.80	19.57	0.909
	Cortone	15	87.80	18.72	
	Placebo	15	85.27	16.36	
Weight (kg)	Vitamin A	15	13.93	8.63	0.629
	Cortone	15	13.35	5.57	
	Placebo	15	11.75	4.18	
The number of days with symptom	Vitamin A	15	3.87	1.92	0.720
	Cortone	15	4.26	3.03	
	Placebo	15	4.60	2.16	
WBC	Vitamin A	15	14000	4000	0.216
	Cortone	15	14000	2800	
	Placebo	15	12000	3600	
PMN	Vitamin A	15	52.50	20.80	0.610
	Cortone	15	56.50	17.20	
	Placebo	15	49.70	17.90	
HB(g/dl)	Vitamin A	15	10.69	1.21	0.894
	Cortone	15	10.75	1.14	
	Placebo	15	10.89	1.18	
Cr	Vitamin A	15	0.59	0.202	0.774
	Cortone	15	0.55	0.118	
	Placebo	15	0.57	0.122	
BUN	Vitamin A	15	20.73	5.58	0.102
	Cortone	15	20.13	4.82	
	Placebo	15	25.21	9.45	
ESR	Vitamin A	15	44.73	26.08	0.991
	Cortone	15	45.53	29.13	
	Placebo	15	44.26	23.19	

*: One Way ANOVA

Table 3. Results of the first and second 99mTc-DMSA scans before and after intervention in the three groups under study

Variable		Groups			P-Value *
		Vitamin A	Cortone	Placebo	
The first 99mTc-DMSA scan (before intervention)	Normal	5 (33.3)	9 (60.0)	9 (60.0)	0.241
	Abnormal	10 (66.7)	6 (40.0)	6 (40.0)	
	Both sides normal	5 (33.3)	9 (60.0)	9 (60.0)	0.516
	Reduced absorption on both sides	1 (6.7)	1 (6.7)	1 (6.7)	
	Normal-scar	6 (40.0)	2 (13.3)	4 (26.7)	
	Normal - reduced absorption	2 (13.3)	3 (20.0)	0 (0)	
	Decreased absorption - scars	1 (6.7)	0 (0)	1 (6.7)	
The second 99mTc-DMSA scan (6 months after intervention)	Normal	12 (80.0)	9 (60.0)	13 (86.7)	0.209
	Abnormal	3 (20.0)	6 (40.0)	2 (13.3)	
	Both sides normal	12 (80.0)	9 (60.0)	13 (86.7)	0.135
	Normal-scar	3 (20.0)	3 (20.0)	2 (13.3)	
	Normal - reduced absorption	0 (0)	3 (20.0)	0 (0)	
Final status	Unchanged	8 (53.3)	13 (86.7)	11 (73.3)	0.016
	Recovery	7 (46.7)	1 (6.7)	4 (26.7)	
	Worsening of the disease	0 (0)	1 (6.7)	0 (0)	

*: Chi square test

Table 4. Results of the first and second 99mTc-DMSA scans before and after intervention according to the three groups under study

Groups			The second 99mTc-DMSA scan			P-Value
			Both sides normal	Normal-scar	Normal-reduced absorption	
The first 99mTc-DMSA scan	Vitamin A	Reduced absorption on both sides	1 (100)	0 (0)	0 (0)	0.001
		Normal-scar	3 (50)	3(50)	0 (0)	
		Normal - reduced absorption	2 (100)	0 (0)	0 (0)	
		Decreased absorption - scars	1 (100)	0 (0)	0 (0)	
	Cortone	Both sides normal	8 (88.9)	1 (11.1)	0 (0)	0.229
		Reduced absorption on both sides	1 (100)	0 (0)	0 (0)	
		Normal-scar	0 (0)	2 (100)	0 (0)	
		Normal - reduced absorption	0 (0)	0 (0)	3 (100)	---------
		Decreased absorption - scars	0 (0)	0 (0)	0 (0)	
	Placebo	Both sides normal	9 (100)	0 (0)	0 (0)	0.096
		Reduced absorption on both sides	1 (100)	0 (0)	0 (0)	
		Normal-scar	2 (50)	2 (50)	0 (0)	
		Normal - reduced absorption	0 (0)	0 (0)	0 (0)	
		Decreased absorption - scars	1 (100)	0 (0)	0 (0)	

*: Chi square test

4. Discussion

The aim of this study was to determine the effect of vitamin A and Corticosteroid in reducing kidney scars in children with APN. The results of our study showed that the recovery rate of the lesions after the

intervention in the group receiving vitamin A (46.7%) was significantly higher than the group treated with Corticosteroid (6.7%) and placebo (26.7%). Also, the results of DMSA scan before and after intervention was statistically significant only for the group receiving vitamin A, so that 46.7% of the total 66.7% patients with abnormal lesions in the primary DMSA scan had improved after the intervention in the secondary DMSA scan. In line with the results of our study, in an interventional study conducted by Sobouti et al. with the aim of investigating the effects of vitamins A or E supplementation along with standard treatment on kidney scars in children with APN, patients were randomly divided into three vitamin A (n=17), E (n=18) and control (n=25) groups and were treated with these supplements for 10 days. Finally, after 6 months, the results of the second 99mTc-DMSA scan showed that the kidney scar in the patients receiving vitamins A and E was significantly less than the control group **(22)**. In a meta-analysis study conducted by Zhang et al. aimed at the effect of vitamin A on renal damage in children with APN, after screening, 4 studies with 248 children aged 1-144 months were included in the analysis and the results showed that the consumption of vitamin A can reduce the risk of renal damage by 47% (relative risk: 0.53, 95 % confidence interval: 0.43- 0.67) **(12)**.

In another study conducted by Kahbazi et al to determine the efficacy of vitamin A supplementation along with standard treatment in improving the symptoms of UTIs and preventing renal scarring in girls with APN. The results showed that vitamin A supplement along with specific antibiotics can reduce kidney scar, fever, and frequency of urination and duration of unfavorable feeding in girls with APN **(8)**. Ayazi et al.'s study, which examined the effect of vitamin A injection in children with pyelonephritis, showed that three months after the intervention, the rate of abnormal findings in the scans of all vitamin A and control groups was 20% and 68%, respectively, which indicates the effect of Vitamin A is significant in reducing kidney scarring **(6)**. In the same way, studies by Dalirani et al has also reported the positive effect of vitamin A administration along with specific antibiotics in reducing renal scarring in children with pyelonephritis **(23)** . Evidence suggests that vitamin A is required for all epithelial cells in body tissues, and vitamin A deficiency can lead to keratinizing metaplasia in respiratory, urinary, and other organs **(24)**. Accordingly, WHO has emphasized the prescription of vitamin A capsules for children every 6 months **(25)**. On the other hand, due to the fact that oxygen free radicals can play an important role in the inflammatory damage to tubulointerstitium, on the other hand, due to the fact that oxygen free radicals can play an important role in the inflammatory damage to tubulointerstitium. It is expected that the administration of antioxidants at the same time as antibiotics will lead to the neutralization of the effect of free oxygen radicals, limiting the oxidative damage to the kidney tissue and ultimately reducing the risk of scarring after pyelonephritis **(12)**.

In our study, Corticosteroid administration had no effect on reducing kidney scar in children with APN compared to placebo which this finding was not consistent with similar studies in this field. For example , Jääskeläinen et al.'s meta-analysis study aimed to determine the effect of corticosteroids on renal scarring in children with APN, showed that supplemental corticosteroids can reduce renal scarring by 35% in these patients (relative risk: 0.65, 95 % confidence interval: 0.44- 0.96) **(11)**. In another study in Taiwan on 84 children under 16 years of age with APN, the scan results six months after the intervention showed that administration of methylprednisolone can reduce renal scarring by 67%, while it was reported by 40% in the control group **(26)**. Sakulchit colleagues also concluded that corticosteroids can be prescribed as an adjunctive treatment in addition to the standard treatment in reducing the scarring of children with acute pyelonephritis **(27)**. Meena et al.'s meta-analysis study also showed that renal scarring was significantly lower in patients receiving corticosteroids than in the control group **(28)**. A clinical trial study by Shaikh et al. on 546 children with APN in the United States showed that administration of corticosteroids along with specific antibiotics for acute pyelonephritis can reduce the risk of kidney scarring compared to antibiotic treatment alone **(29)**. Perhaps an important reason for this discrepancy is the different type of corticosteroid prescribed, because in most of the mentioned studies, methylprednisolone was given to the patients, while in our study, dexamethasone was prescribed.

5. Conclusion

Vitamin A may be effective in reducing kidney scars in children with APN. However, multicenter clinical trial studies with higher sample size are recommended to confirm this finding.

6. Declarations

6.1 Acknowledgments

Thanks to Vice Chancellor of Kermanshah University of Medical Sciences.

6.2 Ethical Considerations

The study was approved by Ethics Committee of Kermanshah University of Medical Sciences (ID-number: IR.KUMS.MED.REC.1401.277) and was registered in IRCT (ID: IRCT20180519039715N5).

6.3 Authors' Contributions

Conceptualization, data collection, statistical analysis, review and editing: AS, MRT and MMK;

Study design, and data analysis: AS and MMK; Writing the original draft: AS, MRT and MMK; Final approval: All authors.

6.4 Conflict of Interest

The authors declare that there are no conflicts of interest.

6.5 Fund or Financial Support

The research budget was supported by the Kermanshah University of Medical Sciences.

6.6 Using Artificial Intelligence Tools (AI Tools)

The authors were not utilized AI Tools.

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How to Cite This Article:

Seyedzadeh A, Tohidi M R, Mohammadi Kamalvand M. The Effect of Vitamin A and Corticosteroid in Reducing Kidney Scars in Children with Acute Pyelonephritis: A Clinical Trial Study. J Adv Med Biomed Res. 2025;33(157):164-71.

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