Research Article **CODEN: AJPCFF** **ISSN: 2321 – 0915**

Asian Journal of Phytomedicine and Clinical Research

Journal home page: www.ajpcrjournal.com

https://doi.org/10.36673/AJPCR.2025.v13.i02.A06

A RETRO-PROSPECTIVE OBSERVATIONAL STUDY ON EFFECT OF BUDESONIDE IN IGA NEPHROPATHY

Ayesha Fatima[1], Mohd Hassan[1], Safwa Nazish*[1], Sameera Saheba[1], A.V. Kishore Babu[1], A. Srinivas Rao[1]

[1*]Bhaskar Pharmacy College, Moinabad, Rangareddy, Telangana, India.

ABSTRACT

Effect of budesonide in IgA nephropathy. After receiving the permission from hospital administration of Asian institute of nephrology and urology a retro prospective observational study was conducted. The patient's data was collected based on inclusion and exclusion criteria in the form of data collection forms. A total of 90 cases were collected to study the effect of budesonide in patients with IgA nephropathy. Pateint diagnosed with IgA nephropathy were prescribed with budesonide, mycophenolate mofetil and other antiproteinuric drug such as angiotensin converting enzyme inhibitor and angiotensin receptor blockers. Patient's serum creatinine, 24hr urine protein, Egfr, Albumin to creatinine ratio. 90 pateints were divided into 3 groups 30 in each based on different treatment regimen, group 1 patients with treatment regimen budesonide, mycophenolate mofetil, ace inhibitors, arbs Group 2 patients with treatment regimen mycophenolate mofetil, ace inhibitor, arbs. Group 3 with treatment regimen ace inhibitors and arbs. Total 35.6% female were part of the study and 64.4% male. Males are more prone to IgA nephropathy. Group I consistently showed the best kidney function, with the lowest creatinine, urine protein, and ACR, and a moderate increase in eGFR. Group III exhibited the slowest improvement across all parameters, indicating a possible delayed response or more severe baseline kidney dysfunction. Group II showed substantial improvements but was not as optimal as Group I. Overall, the intervention had a highly significant impact ($p < 0.001$) on improving kidney function, with Group I benefiting the most.

KEYWORDS

IgA nephropathy, Budesonide, Mycophenolate mofetil, Serum creatinine, Albumin creatinine ratio, Proteinuria and Egfr.

Author for Correspondence:
Safwa Nazish,
Bhaskar Pharmacy College,
Moinabad, Rangareddy, Telangana, India.

Email: Safwanazish771@gmail.com

INTRODUCTION

IgA nephropathy (IgAN) is the most common primary glomerulonephritis, which presents with immunoglobulin A (IgA) deposits in the glomerulus causing kidney inflammation and escalation depending on severity. Proteinuria is one of the clinical hallmarks of IgAN and often associates

with disease severity, or even deterioration into CKD. However, the presence of mild proteinuria often portends a somewhat more indolent course (dependent on level), but not necessarily associated with an absence of risks for further progressive renal deterioration.

Budesonide is a glucocorticoid with rapid first-pass metabolism and targeted release formulations, further exposing it as an applicator of choice for patients with IgAN. These include its capacity to exert mucosal IgA-dependent local immunosuppressive effects within the gut-associated lymphoid tissue

This observational study aims to assess the effect of budesonide in IgAN patients with mild proteinuria, offering insights into its potential role in modifying disease progression in this subgroup, where optimal treatment strategies remain unclear.

MATERIAL AND METHODS

Study design: This study is a single-center retro-prospective cohort observational study.

Study periods: This study was conducted for 6 months

Sample Population: The total number of patients included in the study are 90

STUDY CRITERIA

Inclusion criteria

Adults aged >18 years

Diagnosis of IgA nephropathy confirmed by kidney biopsy.

Exclusion criteria

Active infections or malignancies

Contraindications to corticosteroids, mycophenolate mofetil

Pregnant and breastfeeding women

Source of data collection

The data of patients with supportive laboratory test reports will be collected from the patient's medical records. Laboratory data of before starting the treatment and after 1 month, 3 month will be taken into consideration. The study will be conducted retrospectively and prospectively. Retrospective data will be collected from the medical record department and prospective data will be collected from eligible patient case sheets. Literature for the study was referred from various sources of journals and pharmacological textbooks.

RESULTS AND DISCUSSION

The serum creatinine, egfr, 24hr urine protein, albumin to creatinine ratio were evaluated in patients with IgA nephropathy for specific period of time which was permitted for us, as it was a single point and was conducted in AINU hospital, Banjara hills. A total 90 patients were considered as the sample size.

Table No.1: Data distribution based on Age

S.No	Variable	Groups	N	Mean	SD	F-value	p-value
1	Age	Group I	30	50.9	13.1	2.295	0.107 #
		Group II	30	44.5	11.9		
		Group III	30	44.3	15.4		

Table No.2: Data distribution based on weight

S.No	Variable	Groups	N	Mean	SD	F-value	p-value
1	Weight	Group I	30	79.2	18.2	1.345	0.264 #
		Group II	30	73.6	11.1		
		Group III	30	74.6	11.4		

Table No.3: Data distribution based on gender

S.No	Variable			Groups			Total	χ 2 - value	p-value
				Group I	Group II	Group III			
1	Gender	Female	Count	10	7	15	32	4.752	0.093 #
			%	33.3%	23.3%	50.0%	35.6%		
		Male	Count	20	23	15	58		
			%	66.7%	76.7%	50.0%	64.4%		
2	Total		Count	30	30	30	90		
			%	100.0%	100.0%	100.0%	100.0%		

Table No.4: Comparison between the groups- albumin to creatinine ratio

S.No	Albumin to creatinine ratio	Groups	N	Mean	SD	F-value	p-value
1	Before	Group I	30	85.2	6.7	200.822	0.0005 **
		Group II	30	49.4	2.0		
		Group III	30	78.4	10.7		
2	After 1 Month	Group I	30	72.9	6.1	205.962	0.0005 **
		Group II	30	41.7	1.7		
		Group III	30	76.3	10.9		
3	After 2 Month	Group I	30	61.3	6.2	251.033	0.0005 **
		Group II	30	33.5	1.7		
		Group III	30	74.8	10.8		

Table No.5: Comparison between the groups – serum creatinine

S.No	Sr. Creatinine	Groups	N	Mean	SD	F-value	p-value
1	Before	Group I	30	3.02	0.38	5.249	0.007 **
		Group II	30	2.96	0.46		
		Group III	30	3.30	0.44		
2	After 1 Month	Group I	30	2.31	0.40	23.365	0.0005 **
		Group II	30	2.47	0.46		
		Group III	30	3.04	0.45		
3	After 2 Month	Group I	30	1.62	0.36	64.56	0.0005 **
		Group II	30	1.99	0.43		
		Group III	30	2.82	0.46		

Table No.6: Comparison between the groups – 24hr urine protein

S.No	24 hr Urine Protein	Groups	N	Mean	SD	F-value	p-value
1	Before	Group I	30	2.60	0.38	49.602	0.0005 **
		Group II	30	1.89	0.14		
		Group III	30	2.47	0.31		
2	After 1 Month	Group I	30	1.81	0.36	94.100	0.0005 **
		Group II	30	1.24	0.13		
		Group III	30	2.25	0.31		
3	After 2 Month	Group I	30	1.01	0.37	178.721	0.0005 **
		Group II	30	0.63	0.13		
		Group III	30	2.02	0.33		

Table No.7: Comparison between the groups – Egfr levels

S.No	EGFR	Groups	N	Mean	SD	F-value	p-value
1	Before	Group I	30	22.7	5.0	10.143	0.0005 **
		Group II	30	24.9	5.5		
		Group III	30	19.4	3.7		
2	After 1Month	Group I	30	31.8	8.0	21.162	0.0005 **
		Group II	30	31.5	7.9		
		Group III	30	21.5	4.4		
3	After 2 Month	Group I	30	49.8	14.3	44.422	0.0005 **
		Group II	30	41.4	11.4		
		Group III	30	23.7	5.0		

CONCLUSION

The serum creatinine, Egfr, 24hr urine protein, albumin to creatinine ratio were evaluated in patients with IgA nephropathy for specific period of time which was permitted for us, as it was a single point and was conducted in AINU hospital, Banjara hills. A total 90 patients were considered as the sample size. We have conducted a retro-prospective observational study in patients with IgA nephropathy.

All kidney function markers improved significantly over time in all groups, confirming the effectiveness of the intervention.

Group I consistently showed the best kidney function, with the lowest creatinine, urine protein, and ACR and a moderate increase in Egfr.

Group III exhibited the slowest improvement across all parameters, indicating a possible delayed response or more severe baseline kidney dysfunction.

Group II showed substantial improvements but was not as optimal as Group I.

Overall, the intervention had a highly significant impact ($p < 0.001$) on improving kidney function, with Group I benefiting the most.

ACKNOWLEDGMENT

The authors wish to express their sincere gratitude to Bhaskar Pharmacy College, Moinabad, Rangareddy, Telangana, India for providing necessary facilities to carry out this research work.

CONFLICT OF INTEREST

We declare that we have no conflict of interest.

BIBLIOGRAPHY

1. Fellstrom B C, Barratt J, Cook H, *et al*. Targeted-release budesonide versus placebo in patients with IgA nephropathy (NEFIGAN): A double-blind, randomised, placebo-controlled phase 2b trial, *The Lancet*, 389(10084), 2017, 2117-2127.
2. Lafayette R A, *et al*. Efficacy and safety of a targeted-release formulation of budesonide in patients with primary IgA nephropathy (NefIgArd): 2-year results from a randomized phase 3 trial, *The Lancet*, 402(10396), 2023, 647-658.
3. Ouyang Y, *et al*. A targeted-release formulation of budesonide for the treatment of IgA nephropathy patients with severe renal impairment, *Kidney International Reports*, 9(2), 2024, 123-135.
4. Liao J, Zhou Y, Xu X, Huang K, Chen P, Wu Y, Jin B, Hu Q, Chen G, Zhao S. Current knowledge of targeted-release budesonide in immunoglobulin A nephropathy: A comprehensive review, *Frontiers in Immunology*, 13, 2022, 926517.
5. Smerud H K, Barany P, Lindstrom K, *et al*. Effect of enteric budesonide on proteinuria in patients with IgA nephropathy, *Clinical Journal of the American Society of Nephrology*, 11(6), 2016, 814-822.

6. Hogg R J. Randomized controlled trial of enteric-coated budesonide in children and adolescents with IgA nephropathy, *Pediatric Nephrology*, 36(3), 2021, 599-609.
7. Suzuki H. Targeted intestinal delivery of budesonide in patients with IgA nephropathy: A pilot study, Clinical and Experimental Nephrology, 24(10), 2020, 936-944.
8. Tamura R. Long-term efficacy of budesonide in patients with IgA nephropathy: A retrospective analysis, *Nephrology Dialysis Transplantation*, 34(5), 2019, 903-910.
9. Kawamura T, Yoshimura M, Miyazaki Y, *et al*. A multicenter trial of oral budesonide therapy for IgA nephropathy with moderate proteinuria, *Nephron*, 139(4), 2018, 313-322.
10. Praga M, Navas P, *et al*. Budesonide in the treatment of high-risk IgA nephropathy: A Spanish cohort study, *Clinical Kidney Journal*, 15(3), 2022, 521-531.
11. Li P K, Leung C B, Lai K N, *et al*. Efficacy of budesonide in Chinese patients with IgA nephropathy: A randomized controlled trial, *Kidney International*, 96(2), 2019, 301-311.
12. Schena F P, Manno C, Torres D D, *et al*. Budesonide therapy in IgA nephropathy: A 2-year follow-up study, *Nephrology Dialysis Transplantation*, 32(5), 2017, 778-786.
13. Coppo R, Amore A, *et al*. Budesonide in IgA nephropathy: Targeting the mucosal immune system, *Kidney International Supplements*, 10(3), 2020, 22-27.
14. Cheng J, Zhang W, Zhang X, *et al*. Efficacy and safety of budesonide in the treatment of IgA nephropathy: A meta-analysis of randomized controlled trials, *American Journal of Nephrology*, 54(4), 2023, 278-292.
15. Zhao Y, Zou Y, Wang J, *et al*. A comprehensive review on its potential in IgA nephropathy, *Heliyon*, 10(4), 2024, e12764.

Please cite this article in press as: Safwa Nazish *et al*. A retro-prospective observational study on effect of budesonide in IGA nephropathy, *Asian Journal of Phytomedicine and Clinical Research*, 13(2), 2025, 54-58.