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# A Study on the severity of diabetic retinopathy and macular edema in diabetes mellitus patients on hemodialysis

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Introduction: Diabetes Mellitus (DM) refers to a group of common metabolic disorders that share the phenotype of hyperglycemia. Microvascular abnormalities of DM include both nephropathy and retinopathy. Diabetic retinopathy (DR) tends to deteriorate with failing renal function. Diabetic nephropathy constitutes the most common cause of End Stage Renal Disease (ESRD). ESRD patients require Renal Replacement Therapy (RRT) for survival. Hemodialysis is one of the major methods of RRT. Aim: Aim of the study is to study the prevalence and severity of DR and Diabetic Macular Edema (DME) in diabetic patients on hemodialysis. **Study Design:** A cross sectional observational study. **Methodology:** 105 diabetic patients undergoing hemodialysis for ESRD were subjected to detailed ophthalmic examination with a special emphasis on fundus examination for DR and macularedema. The severity of diabetic retinopathy and macular edema were graded according to International Clinical Diabetic Retinopathy Severity Scale and International Clinical Diabetic Macular Edema Severity Scale respectively. **Results:** In the present study prevalence of DR was 89.8% and prevalence of DME was 23%. Prevalence of Non-Proliferative Diabetic Retinopathy (NPDR) 61.4% was more than Proliferative Diabetic Retinopathy (PDR) 38.6 percent. **Conclusion:** The visual morbidity due to PDR and DME was high among the diabetic patients undergoing hemodialysis.

Keywords: Diabetic Macular Edema, Diabetes Mellitus, Diabetic Retinopathy, Hemodialysis

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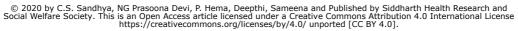
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Note







# Introduction

India is the diabetic capital of the world with second highest number of diabetic cases after China. Chronic complications of Diabetes are due to macrovascular disease and microangiopathy. Microangiopathy in turn leads to retinopathy, nephropathy and neuropathy. Diabetic kidney disease develops in approximately 50% of diabetic patients and is a leading cause of Chronic Kidney Disease (CKD) worldwide [1].

Nearly 20% of type 2 diabetic patients reach ESRD during their lifetime [2]. Diabetic nephropathy constitutes the most common cause of ESRD with 31.2% of ESRD due to DM in India [3]. ESRD patients require Renal Replacement Therapy for survival. Hemodialysis is one of the major methods of RRT [4]. Blindness due to proliferative diabetic retinopathy or maculopathy is approximately 5 times in diabetic patients when compared with non-albuminuric patients [5].

Diabetes Mellitus (DM) refers to a group of common metabolic disorders that share the phenotype of hyperglycemia. Hyperglycemia causes overproduction of superoxide by mitochondrial electron transport chain. Superoxide inhibits enzyme phosphate dehydrogenase of glycolysis and thereby diverts upstream metabolites from glycolysis into 4 major glucose-driven signalling pathways causing hyperglycemic damage.

- -Polyol pathway
- -Hexosamine pathway
- -Diacylglycerol pathway
- -Advanced Glycation End products (AGE) pathway

Increased production of Diacyl Glycerol (DAG) leads to increased activation of protein kinase-C. Protein kinase-C activation leads to vascular abnormalities like altered vascular blood flow, extracellular matrix deposition, basement membrane thickening, increased permeability and neovascularisation.

During periods of glucose fluctuation, genes that encode products that regulate pericyte survival and death are upregulated. Pericyte glutathione content, a basic defence against peroxidation becomes depleted in high glucose conditions. Apoptosis of pericytes leads to cascade of events that results first in background DR, with more extensive loss of pericytes and damage to endothelial cells and with a release of more factors like TGF-  $\beta$ , PDR occurs.

The vascular disruptions of DR/DME are characterized by abnormal vascular flow, disruptions in permeability and /or closure or nonperfusion of capillaries. A hall mark of early DR is the change in the structure and cellular composition of the microvasculature. Endothelial cells are responsible for maintaining the blood retinal barrier, and damage to them results in increased vascular permeability. In early stages of DME, breakdown of inner blood retinal barrier may occur, resulting in accumulation of extracellular fluid in the macula.

DR tends to deteriorate with failing renal function. Diabetic nephropathy constitutes the most common cause of End Stage Renal Disease (ESRD). ESRD patients require Renal Replacement Therapy (RRT) for survival. Hemodialysis is one of the major methods of RRT.

Present study is designed to find the prevalence and to grade the severity of diabetic retinopathy and diabetic macular edema in diabetic patients on hemodialysis for ESRD.

### Aim

 To estimate the prevalence of diabetic retinopathy in diabetes mellitus patients on hemodialysis.

# **Objectives**

- To assess the rate of prevalence of diabetic retinopathy among subjects.
- To grade the severity of diabetic retinopathy among diabetic patients undergoing hemodialysis.
- To assess the prevalence of macular edema and grade the severity of macular edema in the study subjects

# **Materials and Methods**

In the present study a total of 105 patients suffering from diabetes mellitus and undergoing maintenance hemodialysis at NEPHROPLUS Dialysis Centre SVRRGGH Tirupati were evaluated at Ophthalmology Outpatient Department SVRRGG Hospital Tirupati.

Study design: Observational cross-sectional study.

**Study setting:** SVRRGG Hospital Tirupati.

**Study Period:** July 2017 to August 2018 for a period of 1 year.

**Sample Size:** Sample size was calculated with the help of modified Cochran's sample size formula with

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95% confidence levels, 5% margin of error and with expected percentage of diabetic retinopathy in hemodialysis obtained from similar studies. Sample size ranged from 95 to 104. Hence a total of 105 patients were included in the study.

### **Inclusion criteria**

- 01. Patients undergoing hemodialysis for ESRD suffering from diabetes mellitus since the onset of hemodialysis.
- 02. Patients aged more than 18 years.

### **Exclusion criteria**

- 01. Subjects undergoing hemodialysis for acute kidney injury and other acute renal disorders.
- 02. Subjects who are debilitated and unable to move.
- 03. Subjects with media opacities preventing detailed fundus examination.
- 04. Subjects not willing to participate in the study.

**Study subjects:** All subjects who meet inclusion and exclusion criteria.

## Study methods

- 01. Patients who meet inclusion exclusion criteria were evaluated at Ophthalmology OPD.
- 02. Best Corrected Visual Acuity for both near and distance was recorded using Jaegers chart and Snellen's chart respectively.
- 03. Anterior segment examination was done with Slit lamp biomicroscope
- 04. Dilatation of pupils was done with plain tropicamide 1% eye drops.
- 05. Fundus examination was done with the help of direct ophthalmoscope, 90D lens under slit lamp and with indirect ophthalmoscope wherever necessary.
- 06. Diabetic retinopathy and Diabetic macular edema were graded according to International Clinic Diabetic Retinopathy Disease Severity Scale and International Clinical Diabetic Macular Edema Disease Severity Scale respectively.

Table-1: International classification of diabetic retinopathy [6].

,	Findings observable on dilated ophthalmoscopy
No apparent retinopathy	No abnormalities
Mild non-proliferative diabetic	Microaneurysms only
retinopathy (NPDR)	

Moderate	More than just microaneurysms but less than severe non
non	proliferative diabetic retinopathy
proliferative	
diabetic	
retinopathy	
Severe non	Any of the following: More than 20 intraretinal hemorrhages
proliferative	in each of four quadrants Definite venous beading Prominent
diabetic	intra retinal microvascular abnormalities in 1 quadrant And
retinopathy	no signs of proliferative retinopathy
Proliferative	One or more of the following: Neovascularisation: Vitreous or
diabetic	preretinal haemorrhage
retinopathy	
(PDR)	

Table-2: international clinical diabetic macular edema disease severity scale [6].

Proposed disease severity	Findings observable on dilated	
level	ophthalmoscopy	
Diabetic macular edema	No apparent retinal thickening or hard	
apparently absent	exudates in posterior pole	
Diabetic macular edema	Some apparent retinal thickening or hard	
apparently present	exudates in posterior pole	

If diabetic macular edema is present it can be classified as

Table-3: International classification of diabetic macular edema [6].

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Proposed disease	Findings observable on dilated ophthalmoscopy		
severity level			
Mild diabetic	some retinal thickening or hard exudates in posterior		
maculr edema	pole but distant from the centre of the macula		
Moderate diabetic	retinal thickening or hard exudates approaching the		
maculr edema	centre of the macula but not involving the centre.		
Severe diabetic	retinal thickening or hard exudates involving the centre		
maculr edema	of macula		

**Study analysis:** Data was analyzed with MS Excel using software IBM SPSS version 2.1and statistical significance was indicated by p value.

# Results

105 patients suffering from diabetes mellitus undergoing maintenance hemodialysis for ESRD were evaluated in the present study. Among the total 210 eyes of 105 patients, 14 eyes were excluded due to hazy media which prevented detailed fundus examination. Hence a total of 196 eyes of diabetic patients undergoing hemodialysis were evaluated (Table 4).

Table 4: Distribution of subjects.

Total number of patients	
Eyes with hazy media	
Total number of eyes	

**Duration of dialysis**: All the diabetic patients included in the present study had been undergoing hemodialysis for the duration ranging from 2 months to 8 years (Table 5). Majority of the patients had been undergoing hemodialysis for a duration of 1 month to 2 years. Mean duration of hemodialysis of the patients in the present study was found to be 1.5 years with a standard deviation of  $\pm 0.8$ .

Table 5: Dialysis duration.

Dialysis Duration (years)	No. of Patients
<1	31
1-2	41
3-4	18
5-6	9
7-8	6

**Prevalence of diabetic retinopathy:** In 196 eyes of 105 diabetic patients included in the study. The number of eyes with no diabetic retinopathy were 20 (10.2%) and belonged to no DR grade. Hence the prevalence of diabetic retinopathy in the present study was found to be 89.79% (Table 6).

Table 6: Prevalence of diabetic retinopathy

Total	Eyes with DR	Eyes with No DR
196 (eyes)	176	20
105 (Patients)	95 (Patients)	10 (Patients)

**Grading of diabetic retinopathy**: Grading of diabetic retinopathy changes was done according to international clinical diabetic retinopathy disease severity scale [6]. In 196 eyes of 105 diabetic patients included in the study. 20 eyes (10.2%) with no diabetic retinopathy changes belonged to no DR grade. Mild NPDR changes were found in 16 eyes (8.1%), Moderate NPDR changes were found in 54 eyes (27.6%), Severe NPDR changes were found in 38 eyes (19.4%) and PDR changes were present in 68 eyes (34.7%) (Table 7).

Prevalence of Proliferative Diabetic Retinopathy was higher compared to other grades with 34.7%. Non proliferative diabetic retinopathy including mild, moderate and severe NPDR grades together constituted 55.1%.

Table 7: Grading of diabetic retinopathy.

Grade	Number of eyes	Percentage of eyes
No DR	20	10.2%
Mild DR	16	8.1%
Moderate DR	54	27.6%
Severe DR	38	19.4%
PDR	68	34.7%
Total	196	100%

**Diabetic macular edema**: Diabetic macular edema was found in 45 eyes out of 196 eyes of 105 patients included in the study. Hence prevalence of DME in the present study was found to be 23% (Table 8).

Prevalence of severe DME grade was more (60%) compared to other grades in the present study (Table 9).

Table 8: Prevalence of Diabetic macular edema.

Grade	No. of eyes
Diabetic macular edema apparently absent	151
Diabetic macular edema apparently present	45

Table 9: Grading of DME.

Grade of DME	Number of eyes	Percentage of eye
Mild DME	3	6.7%
Moderate DME	15	33.3%
Severe DME	27	60%
Total	45	100%

# Relationship of Hemodialysis Duration with Diabetic

**Retinopathy Grade:** Patients included in the present study were undergoing maintenance hemodialysis for a duration ranging from 2 months to 8 years.

Statistical significance of association between hemodialysis duration and DR grade was tested with Chi-Square Test and the p-value was found to be >0.05. Hence there was no statistically significant association between duration of hemodialysis and DR grade (Table 10).

Table 10: Relationship of Diabetic retinopathy grade and dialysis duration.

Dialysis Duration (years)	No DR (eyes)	Mild NPDR (eyes)	Mod NPDR (eyes)	Severe NPDR (eyes)	PDR (eyes)	Total (eyes)
< 3	20(10.2%)	16 (8%)	38 (%)	23 (11.7%)	47 (24%)	144 (73.5%)
≥ 3	-	-	16 (8%)	15 (7.7%)	21 (10.7%)	52 (26.5%)
Total	20(10.2%)	16 (8%)	54 (27.6%)	38 (19.4%)	68 (34.7%)	196 (100%)

**Best Corrected Visual Acuity (BCVA):** BCVA of all the patients in the present study was acquired with the help of Snellen's chart. 83 eyes (42.3%) out of 196 eyes included in the study had good BCVA of better or equal to 6/18 in Snellen's chart (Table 11).

Table 11: Best Corrected Visual Acuity (BCVA)

BCVA	Number of Eyes	Percentage of eyes
>/=6/18	83	42.3%
6/24 to 6/60	83	42.3%
<6/60 to >3/60	5	2.6%
3/60 to 1/60	8	4%
<1/60 to PL	17	8.7%

# \* PL- Perception of Light

Out of 45 eyes with DME, only 3 eyes had good vision with BCVA better than or equal to 6/18. Remaining 42 eyes had low vision with BCVA of 6/24 to 6/60. PDR changes were found in 68 eyes out of 196 eyes included in the present study.

Of these 68 eyes BCVA was better or equal to 6/18 in 13 eyes, 6/24 to 6/60 in 25 eyes, worse than 6/60 to better than 3/60 in 5 eyes, 3/60 to 1/60 in 8 eyes and worse than 1/60 in 17 eyes. Only 83 eyes out of 196 eyes included in the study had good vision with BCVA better than or equal to 6/18. Remaining 113 eyes had BCVA less than 6/18. Poor vision with BCVA worse than 6/60 was found in 30 eyes.

All these 30 eyes had PDR changes and the poor vision was due to large vitreous hemorrhage or preretinal hemorrhage in front of macula or Tractional retinal detachment involving macula or combined Tractional Retinal Detachment and /Rhegmatogenous Retinal Detachment. 83 eyes had BCVA of 6/24 to 6/60, of these 42 eyes had DME.

Remaining eyes had BCVA less than 6/18 due to miscellaneous causes like Age Related Macular Degeneration, glaucoma, small central lenticular or corneal opacity etc (Table 12).

Table 12: Best Corrected Visual Acuity (BCVA) in Proliferative Diabetic Retinopathy (PDR) and Diabetic macular edema (DME)

BCVA	PDR	DME
>/=6/18	13	3
6/24 to 6/60	25	42
<6/60 to >3/60	5	_
3/60 to 1/60	8	-
<1/60 to PL	17	-

# Discussion

Chronic renal failure is a slow progressive loss of kidney function over a period of several years. End Stage Renal Disease is the final stage of chronic renal failure. Most common causes of ESRD are Diabetes Mellitus and Hypertension.

Patients with ESRD cannot survive without a renal replacement therapy. The most commonly used renal replacement therapy is hemodialysis. Diabetic retinopathy is a major cause of visual impairment among patients suffering from diabetes mellitus with ESRD.

The present study was an observational crosssectional hospital-based study on patients suffering from Diabetes Mellitus with ESRD undergoing maintenance hemodialysis.

In the present study, a total of 105 patients suffering from diabetes mellitus undergoing hemodialysis for ESRD were evaluated. 6 patients had type 1 diabetes mellitus and 99 patients had type 2 diabetes mellitus.

**Duration of hemodialysis:** All the diabetic patients included in the present study had been undergoing hemodialysis for the duration ranging from 2 months to 8 years. Majority of the patients had been undergoing hemodialysis for a duration of 1 month to 2 years (68.6%). Mean duration of hemodialysis of the patients in the present study was found to be  $1.5 \pm 0.8$  years.

**Prevalence of diabetic retinopathy:** Out of the total 210 eyes of 105 patients, 14 eyes were excluded from the study due to media opacities which prevented fundus examination. 196 eyes were evaluated in the present study. 176 eyes (89.8%) had DR changes out of 196 eyes. 20 eyes had no diabetic retinopathy changes. Prevalence of diabetic retinopathy among diabetic patients on hemodialysis in the present study was found to be 89.8%.

Comparison of prevalence of DR: Prevalence of DR in ESRD patients with DM was found to be 100% (all eyes of 7 DM cases) in Bajracharya et al study [7]. Prevalence of DR in diabetic patients on hemodialysis is 71.4% in Malliswari et al study [8] and 73.68% (14 of 19) in Mahmood et al study [9]. Prevalence of DR was100% in Imran et al study [10]. In Vrabec et al study [11], the prevalence of DR was 71.4% (5 out of 7).

Due to small sample size, prevalence rate may not be appropriate in Bajracharya et al study [7] and Vrabec et al study [11]. The prevalence rates of DR in the present study are comparable to the other studies (Table 13).

Table 13: Comparison of prevalence of diabetic retinopathy.

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Study	Prevalence of DR in ESRD patients with
	DM
Present study	89.8%
Bajracharya et al study	100%
[7]	
Malliswari et al study [8]	71.4%
Mahmood et al study [9]	73.68%
Imran et al study [10]	100%
Vrabec et al study [11]	71.4%

Grading of diabetic retinopathy: In the present study, 196 eyes of 105 patients were evaluated. Grading of DR was done based on International Clinical Diabetic Retinopathy Disease Severity Scale. According to this classification, 20 eyes (10.2%) had no DR grade changes, 16 eyes had mild NPDR grade changes, 54 eyes (27.6%) had moderate NPDR grade changes, 38 eyes (19.4%) had severe NPDR grade changes and 68 eyes (34.7%) had PDR grade changes. Prevalence of Proliferative Diabetic Retinopathy was higher compared to other grades with 34.7%.

Comparison of grades of DR: In the present study, 20 eyes out of 196 eyes included in the study had no Diabetic Retinopathy changes in their fundus. Hence a total of 176 eyes had Diabetic Retinopathy. Of these 176 eyes, NPDR changes including mild NPDR, moderate NPDR and severe NPDR grades were found in 108 eyes (61.4%). PDR changes were found in 68 eyes (38.6%). In Bajracharya et al study [7], prevalence of NPDR was found to be 71.2% and PDR 28.5%. In Dahli P et al study [12], prevalence of NPDR was 75% and PDR was 25%.

In Mithun Thulasidas et al study [13], prevalence of NPDR was 70.4% and PDR was 29.4%. In Malliswari et al study [8] NPDR constituted 76.5% and PDR 23.5%. In Jasmine et al study [14], NPDR was 84.05% and PDR was 16.08%. In Suman S et al study [15], prevalence of NPDR was found to be 75% and PDR 25%. Prevalence of NPDR was 68.5% and PDR 31.3% in Samreen Jamal et al study [16]. Prevalence of NPDR was 80% and PDR was 20% in Vrabec et al study [11].

In all these studies, NPDR percentage was more than PDR percentage which is similar to the present study (Table 14).

Table 14: Comparison of prevalence of grades of DR in ESRD patients

Study	NPDR Percentage	PDR Percentage
Present study	61.4	38.6
Bajracharya et al study [7]	71.2	28.5
Dahlia P et al study [12]	75	25
Mithun thulasidas et al [13]	70.4	29.4
Malliswari et al study [8]	76.5	23.5
Jasmine et al study [14]	84.05	16.08
Suman et al study [15]	75	25
Sameern et al study [16]	68.5	31.3
Vrabec et al study [12]	80	20

**Diabetic macular edema:** Diabetic Macular Edema changes were found in 45 eyes out of total 196 eyes of 105 patients included in the present study. Hence the prevalence of DME in the present study was 23%. Percentage of DME was 17.5% in Suman S et al study [15] and 15% in Malliswari et al study [8] which was almost similar to the present study (Table 15).

Table 15: Comparison of prevalence of diabetic maculopathy.

Study	Diabetic Maculopathy
Present study	23%
Malliswari et al study [8]	15%
Suman et al study [15]	17.5%

DME changes were graded according to International Clinical Diabetic Macular Edema Disease Severity Scale. Mild DME changes were found in 3 eyes out of 45 eyes (6.7%). Moderate DME changes were found in 15 eyes (33.3%) and Severe DME changes were found in 15 eyes (60%). Prevalence of severe DME grade changes was more (60%) compared to other grades in the present study.

DME was found in 13 eyes (28.8%) with moderate NPDR grade fundus changes. 21 eyes (46.7%) with severe NPDR grade changes had DME and 11 eyes (24.5%) with PDR had DME.DME was found predominantly in eyes with DR of severe NPDR grade (46.7%)

# Relationship of hemodialysis duration with diabetic

**Retinopathy grade:** No statistically significant association was found between the duration of hemodialysis and DR grade in the present study.

Best Corrected Visual Acuity: Out of all 196 eyes of 105 patients evaluated in the present study, 42.3% (83 of 196 eyes) of eyes had good visual acuity up to 6/18 or better than 6/18. Another 42.3% (83 of 196 eyes) of eyes had visual acuity in the range of 6/24 to 6/60. Remaining 15.4% (30 of 196) eyes had visual acuity less than 6/60. In Suman S et al study [15], BCVA was better or equal to 6/18 in 39.41% eyes. 6/24 to 6/60 in 27.56% of eyes and worse than 6/60 to PL in 33% of eyes. In Jasmine et al study [14] BCVA was better or equal to 6/18 in 60.5% eyes, 6/24 to 6/60 in 23.5% eyes and worse than 6/60 in 16% eyes. In Malliswari et al study [8], BCVA was better or equal to 6/18 in 37% eyes, 6/24 to 6/60 in 19% eyes and worse than 6/60 in 44% eyes (Table 16).

Table 16: Comparison of BCVA in ESRD patients

Study	≥6/18	6/24 to6/60	<6/60 to pl +ve
Present study	42.3%	42.3%	15.3%
Malliswari et al study [8]	39.41%	27.56%	33%
Suman et al study [15]	37%	19%	44%
Jasmine et al study [14]	60.5%	23.5%	16%

DME was the cause for visual impairment in 42 eyes. All the 42 eyes were in the range of 6/24 to 6/60 constituting 21% of eyes included in the study. In PDR eyes advanced changes like TRD involving macula, combined TRD and RRD, large vitreous hemorrhage and large preretinal hemorrhage in front of macula were the causes for severe visual impairment (<6/60) in 17 eyes (9%).

BCVA was good, better or equal to 6/18 in 13 eyes with PDR and 3 eyes with DME. Preservation of this good visual acuity in these eyes would have been possible with appropriate treatment and timely intervention.

# Strengths of the Study

- The present study helped in identifying undiagnosed cases of diabetic retinopathy thereby providing appropriate treatment and timely intervention when ever needed.
- This study helped in increasing awareness among hemodialysis patients about the need for regular ophthalmic examinations.
- Prevalence of diabetic retinopathy among hemodialysis patients was studied in other studies. In the present study prevalence of DR and DME among diabetic patients undergoing hemodialysis was estimated and severity was graded.

# Limitations of the study

- Prevalence rate might have been underestimated or overestimated due to small sample size.
- The status of Diabetic Retinopathy of the patients at the time of initiation of hemodialysis was not known.
- Influence of metabolic abnormalities associated with chronic kidney disease like anemia and uremia on retinopathy was not taken into consideration.
- There was no follow up of the patients.

# Conclusion

Preventable visual morbidity due to DME and PDR is found to be significant among diabetic patients on hemodialysis in the present study.

This emphasises the importance of periodic ophthalmic examination in patients on hemodialysis for ESRD due to DM which can help in early diagnosis of sight threatening diabetic retinopathy and maculopathy.

Appropriate and timely ophthalmic intervention in such patients can go a long way in preventing visual loss in these patients.

# What the study adds to the existing knowledge?

The previous similar studies concentrated mainly on prevalence of DR and severity of DR in diabetic patients who are on hemodialysis. In the present study in addition to above aspect the current study also tried to concentrate on the prevalence of macular edema and graded the severity of macular edema in diabetic patients on hemodialysis.

# Author's contribution

**Dr. C.S. Sandhya:** Selection of the topic for the study, Guided the residents through all the steps of the study. Finalisation of manuscript.

**Dr. Gnana Prasoona:** Coordinated the work of residents throughout study process. Prepared and finalised the manuscript.

**Dr. Hema:** Identified the study subjects, took history and done all the necessary investigations and reported the same to guide and co-guide of the study.

- **Dr. Deepthi:** Identified the study subjects, took history and done all the necessary investigations and reported the same to guide and co-guide of the study.
- **Dr. Sameena:** Identified the study subjects, took history and done all the necessary investigations and reported the same to guide and co-guide of the study.

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