

A Comparative Evaluation of Megadose Methylprednisolone with Dexamethasone for Treatment of Primary Typical Optic Neuritis

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Abstract: ***Aim:** To compare the efficacy of intravenous methylprednisolone and intravenous dexamethasone on visual recovery, in patients of primary typical optic neuritis and to evaluate the side-effects of these drugs. **Materials and Methods :** The present prospective, institution based study was carried out in the Department of Ophthalmology, Assam Medical College and Hospital, Dibrugarh from 1st June 2016 to 31st May 2017 on 60 patients of acute optic neuritis presenting within eight days of onset and with visual acuity less than 6/18 (20/60) in the affected eye where consecutive patients were alternately divided into two groups, Group I receiving intravenous Dexamethasone and Group II receiving intravenous Methylprednisolone. **Result:** The visual acuity and colour vision showed improvement in all the patients of both the dexamethasone and methylprednisolone group so that at the end of three months follow up, 27 eyes (87.09%) in group I, 26 (86.66%) eyes in group II had a vision of 6/6-6/18 and . 22 (70.98%) eyes in group I, 23 (76.66%) eyes in group II had normal colour vision. Visual fields returned to normal in 12 eyes (38.70%) and 10(33.33%) eyes in group I and II respectively. **Conclusion:** The study showed that intravenous dexamethasone and intravenous methylprednisolone therapy to be equally effective in treatment of primary typical optic neuritis as recommended by the ONTT study.*

Keywords: Methylprednisolone , Dexamethasone, Optic neuritis

1. Introduction

An inflammation of the optic nerve is known as optic neuritis¹. The term implies involvement of any part of optic nerve by a disease process that impairs nerve conductivity as indicated by loss of visual acuity and changes in the field of vision². It may be divided clinically into: (i) papillitis, (ii) neuroretinitis and (iii) retrobulbar neuritis¹. In papillitis there is ophthalmoscopically visible field changes whereas in retrobulbar neuritis there is no such obvious changes apprehensible.

Based on aetiology, optic neuritis can be divided into: (i) demyelinating, (ii) parainfectious, (iii) infectious and (iv) autoimmune³. It may be associated with a variety of systemic autoimmune disorders, but the most common form, acute demyelinating optic neuritis, is best known for its association with multiple sclerosis⁴. On the basis of pathogenesis it can be broadly classified to be due to inflammatory, degenerative or ischemic process².

The symptom and clinical signs of papillitis as well as that of retrobulbar neuritis are typical. The disease is usually unilateral and progress rapidly during one to eight day with severe loss of vision. In retrobulbar neuritis local pain may be felt on moving the eye. The pain is increased by pressure upon the globe and there may be headache and neuralgia. In papillitis optic disc is at first hyperemic, the margin become blurred, swelling and oedema ensue which spread onto the retina. The retinal veins become engorged and tortuous, exudates accumulates upon the disc and in the retina sometimes forming a macular fan. There may be fine vitreous opacities. Swelling of the disc rarely exceeds 2-3 dioptre. In retrobulbar neuritis, one the other hand, there is no ophthalmoscopically visible changes and the condition may be truly defined as a disease wherein neither the surgeon nor the patients sees anything⁵. In the course of

management it has been seen that tendency for recovery is one of the characteristics of optic neuritis.

Optic neuritis is known to improve without treatment though it may also result in long-lasting defects in visual acuity and abnormalities in contrast sensitivity, color vision, stereopsis, light sensitivity, visual fields, papillary responses, optic disc appearance and visual evoked potentials^{6,7}. The treatment of optic neuritis has always been controversial regarding the use of steroids. Steroids by oral, retrobulbar and intravenous routes have been used. Though corticosteroids are thought to be of little benefit in altering the eventual visual outcome, it may shorten the clinical course.

2. Materials and Methods

This work entitled —A comparative evaluation of megadose methyl -prednisolone with dexamethasone for treatment of primary typical optic neuritis has been conducted in the Department of Ophthalmology, Assam Medical College and Hospital, for one full calendar year (including three months follow-up) from 1st June 2016 to 31st May 2017.

The prospective, hospital based study was carried out on all the patients of acute optic neuritis presenting within eight days of onset and with visual acuity less than 6/18 (20/60) in the affected eye where consecutive patients were alternately divided into two groups and received the following treatment:

- **Group I:** Intravenous dexamethasone 200 mg (in 150 ml 5% dextrose solution) given over one and a half to two hours once a day for three days.
- **Group II :** Intravenous methylprednisolone 250 mg/six-hourly. i.e. 1000mg (in 150 ml 5% dextrose solution) given over one and a half to two hours for three days followed by oral prednisolone for 11 days.

Group I consisted of 30 patients and Group II consisted of 30 patients. The intravenous steroids was infused by slow intravenous drip over a period of one and a half to two hours. The pulse and blood pressure was recorded prior to the institution of pulse therapy and monitored through-out at 30-min intervals till the completion of the infusion and for one hour thereafter. The doses was repeated on day 2 and day 3. The patients in both groups were examined every day during the institution of treatment and later at one week, one month and three months.

Selection of Cases

The patients were selected on the basis of detailed history of presenting symptoms, a thorough clinical examination including ophthalmoscopic finding and visual field charting and pertinent investigations.

Inclusion Criteria:

- Clinical diagnosis of a first episode of unilateral or bilateral optic neuritis (ON) in age group more than 14 years.
- Visual acuity <6/18 (20/60) in the affected eye.

Exclusion Criteria:

- All cases with known systemic disease other than multiple sclerosis that might be the cause of the optic neuritis were excluded.
- Cases were also excluded if they had a history of previous attacks of optic neuritis or diagnosis of multiple sclerosis for which the patient had already received corticosteroids or evidence of optic disc pallor in the currently affected eye.
- Cases with pre-existing ocular abnormalities that might affect assessment of visual functions.
- Evidence of any systemic condition for which corticosteroids would be contraindicated also excluded.

Procedures Planned

- (1) History taking, (as per proforma)
- (2) Clinical examination, (as per proforma)
- (3) Direct and Indirect Ophthalmoscopic examination.
- (4) MRI of brain with orbit.

A detailed history related to the disease had been taken in all the cases. A thorough systemic and neurological examination was performed. A complete ophthalmic examination was performed to evaluate the anterior segment and posterior segment with slit-lamp biomicroscopy and indirect ophthalmoscopy. The pupillary reactions, visual acuity and fundus findings were assessed before and during institution of treatment. Color vision, and Humphrey visual fields were recorded for all patients after giving full refractive correction whenever the visual acuity permitted. Visual acuity was examined for distant and near vision, with and without glasses. For distant vision Snellen’s visual acuity charts (at a distance of 6m) and for near vision Jaeger’s print chart was used. Colour vision was recorded using Ishihara pseudoisochromatic color vision plates where the visual acuity permitted the assessment of it. The color vision was quantified Humphrey full threshold technique using Humphrey field analyser for both the eyes were done. Magnetic resonance imaging was done where deemed a necessity and in those who could afford the investigation.

A total of 60 patients were included in the study. The patients were randomly divided into two groups of 30 each, Group I received intravenous Dexamethasone therapy while Group II received intravenous Methylprednisolone therapy. 36 eyes were involved in group I and 37 eyes were involved in group II. Three months of follow-up was completed in 31 (26 patients) eyes in group I and 30 (24 patients) eyes in group II.

Statistical Analysis

Data were recorded on a pre-designed proforma. Mean and SD summarized variables in two groups. Statistical analysis was done using methods such as student’s t test, Chi-square test for the different clinical parameters, as appropriate. In this study *p* value <0.05 was considered statistically significant.

3. Results and Observations

Table 1: Age Distribution

Age Group (in years)	Group-I (Dexamethasone)		Group-II (Methyl Prednisolone)		p value
	n	%	n	%	
<20	4	13.33	3	10.00	0.893 (NS)
20—29	8	26.67	7	23.33	
30—39	11	36.67	14	46.67	
40—49	5	16.67	4	13.33	
50—59	1	3.33	1	3.33	
60—69	1	3.33	1	3.33	
≥ 70	0	0.00	0	0.00	
TOTAL	30	100.00	30	100.00	
Mean ± S.D.	31.57 ± 10.31		31.93 ± 10.71		

In the present study, age of the patients ranged from 18 to 60 years in group I while 17 to 60 years in group II. The mean age of presentation in group I is 31.57±10.31 and 31.93 ± 10.71 in group II. Most of the cases were between 30-39 years of age in both the groups, 11 (36.6%) in group I and 14 (25%) in group II.

Table 2: Sex Distribution

Sex	Group-I		Group-II		p value
	n	%	n	%	
Male	13	43.33	14	46.67	0.79525
Female	17	56.67	16	53.33	
Total	30	100.00	30	100.00	
Ratio (Male:Female)	1:131		1:14		

Group I consisted of 13 (43.3%) males and 17 (56.6%) females and group II consisted of 14 (46.6%) males and 16 (53.3) females. The male: female ratio in Group I and II are 1: 1.31 and 1: 1.4 respectively.

Table 3: Laterality

Laterality	Group-I		Group-II		Value
	n	%	n	%	
Unilateral	24	80.00	23	76.67	0.754001
Bilateral	6	20.00	7	23.33	
TOTAL	30	100.00	30	100.00	

Unilateral optic neuritis dominated the study group. There were 24 (80%) patients in group I and 23 (76.6%) in group II with unilateral optic neuritis. Bilateral optic neuritis was

found in 6 (20%) patients in group I and 7 (23.3%) patients in group II.

Table 4: Presenting Complaints

Presenting Complaints	Group-I		Group-II	
	n	%	n	%
Diminution of Vision	30	100.00	30	100.00
Eye Pain	15	50.00	17	56.67
Headache	2	6.67	3	10.00

All the patients in both the groups presented with sudden diminution of vision. Eye pain was present in 15 (50%) cases in group I and 17 (56.67%) cases in group II. Headache was present in 2 (6.67%) in Group I and 3 (10%) in group II.

Table 5: Clinical Diagnosis

Clinical Diagnosis	Group-I		Group-II	
	n	%	n	%
Papillitis	21	58.33	24	64.86
Retrolbulbar Neuritis	14	38.88	12	32.48
Neuroretinitis	1	2.77	1	2.70
Total Number of Affected Eyes	36		37	

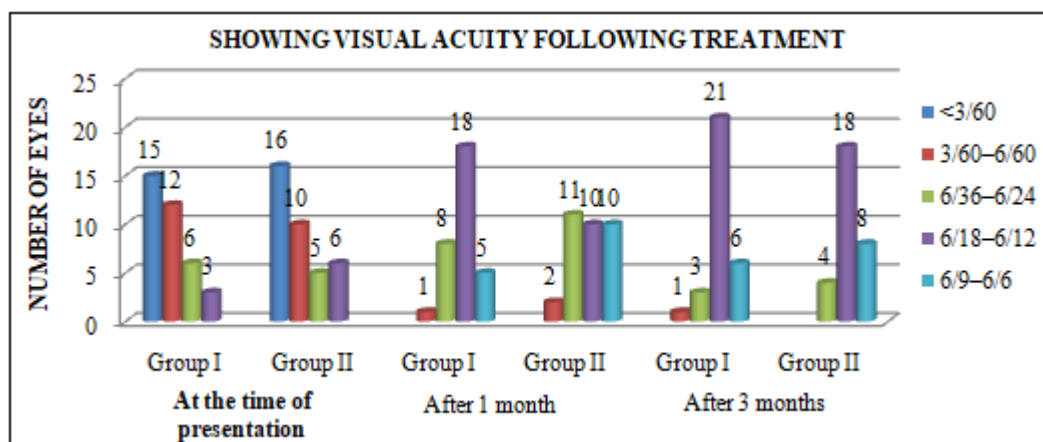
Out of 36 affected eyes in group I, 21 (58.33%) eyes were diagnosed as papillitis and 14 (38.88%) eyes were diagnosed as retrolbulbar neuritis and 1 (2.77%) eye with neuroretinitis. In group II, out of 37 affected eyes, 24 (64.86%) eyes were diagnosed as papillitis, 12 (32.48%) as retrolbulbar optic neuritis and 1 (2.70%) eye was diagnosed to have neuroretinitis at the time of presentation.

Table 6: Visual Acuity of Eyes Following Treatment in the two Groups

Visual Acuity	At the Time of Presentation		Day3		Day 7		1 Month		3 Months	
	Group I	Group II	Group I	Group II	Group I	Group II	Group I	Group II	Group I	Group II
<3/60	15	16	8	7	3	1	-	-	-	-
3/60-6/60	12	10	11	13	4	10	1	2	1	-
6/36-6/24	6	5	14	9	13	12	8	11	3	4
6/18-6/12	3	6	4	7	12	6	18	10	21	18
6/9-6/6	-	-	1	1	4	8	5	10	6	8
Total Number of Eyes	36	37	36	37	36	37	34	33	31	30
<i>p value</i>	0.731146		0.712686		0.139506		0.191439		0.778713	

At the time of presentation in group I, 15 eyes had vision less than 3/60 and 12 eyes had vision of 3/60-6/60 and 6 eyes had vision of 6/36-6/24. At subsequent follow ups, the visual acuity showed improvement in all patients so that at the end of three months follow up, 27 eyes (87.09%) out of 31 involved eyes had a vision of 6/6-6/18. In group II 16 eyes had vision less than 3/60, 10 eye had vision of 3/60-6/60 and 5 eyes had vision of 6/36-6/24. At subsequent follow ups, the visual acuity showed improvements in all patients so at the end of 3 months follow up 26 (86.66%) eyes out of 30 eyes had a vision of 6/6-6/18.

In group I, 15 eyes had vision less than 3/60 and 12 eyes had vision of 3/60-6/60 and 6 eyes had vision of 6/36-6/24 at the time of presentation. At the end of three months follow up, 27 eyes (87.09%) out of 31 involved eyes had a vision of 6/6-6/18. In group II 16 eyes had vision less than 3/60, 10 eye had vision of 3/60-6/60 and 5 eyes had vision of 6/36-6/24. At subsequent follow ups, the visual acuity showed improvements in all patients ,so at the end of 3 months follow up 26 (86.66%) eyes out of 30 eyes had a vision of 6/6-6/18.



The p value were 0.731, 0.712, 0.139, 0.128, 0.760 respectively for the two groups at the time of presentation, day 3, day 7, 1month, 3months follow up respectively which was statistically insignificant. Hence dexamethasone and

methylprednisolone have equal efficacy in the outcome of the visual acuity upto 3 months follow up.

Table 7: Colour Vision at Presentation and on Subsequent Follow Ups

Colour Vision	At the Time of Presentation		Day3		Day 7		1 Month		3 Months	
	Group I	Group II	Group I	Group II	Group I	Group II	Group I	Group II	Group I	Group II
Severe Colour Deficit.	27	26	17	18	8	9	4	4	2	2
Moderate Colour Deficit	9	11	18	17	22	23	15	18	7	5
Normal	-	-	-	-	6	5	15	11	22	23
Total Number of Eyes	36	37	36	37	36	37	34	33	31	30
<i>p value</i>	0.65055		0.81107		0.81107		0.785307		0.646171	

Among the study population, in group I, 27 eyes colour vision could not be assessed because of poor visual acuity, 9 patients had abnormal colour vision. At the end of three months after treatment with intravenous dexamethasone, 22 (70.98%) eyes out of 31 affected eyes in group I had normal colour vision while 9 (29.03%) eyes had abnormal colour vision.. In group II, 11 eyes had abnormal colour vision while colour vision testing could not be done in 26 eyes

because of poor visual acuity. After treatment with intravenous methylprednisolone, colour vision showed improvement in all eyes so that at the end of three months follow up, 23 (76.66%) eyes had normal colour vision while 7 (23.33%) eyes had abnormal colour vision.

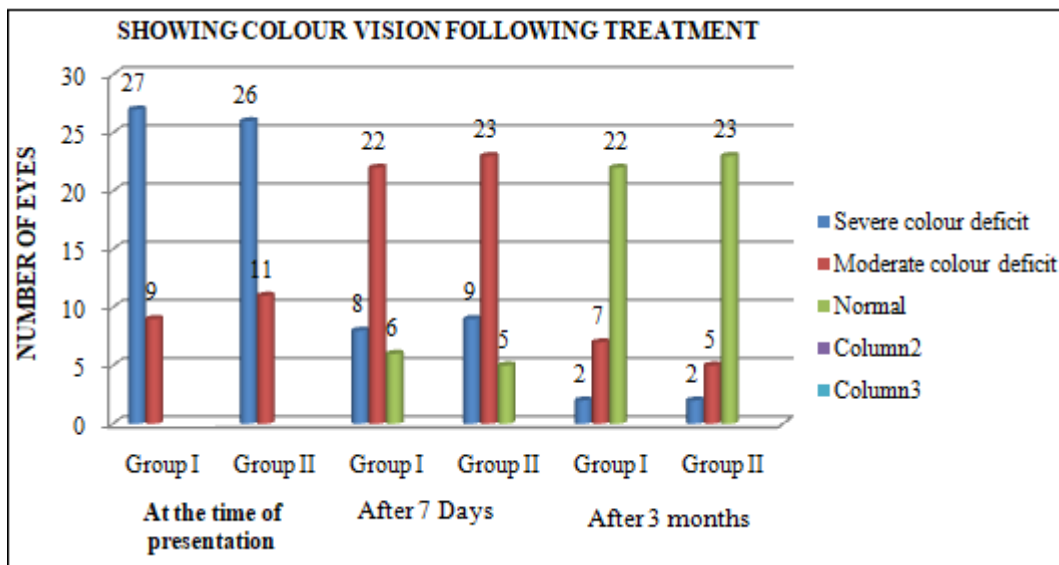
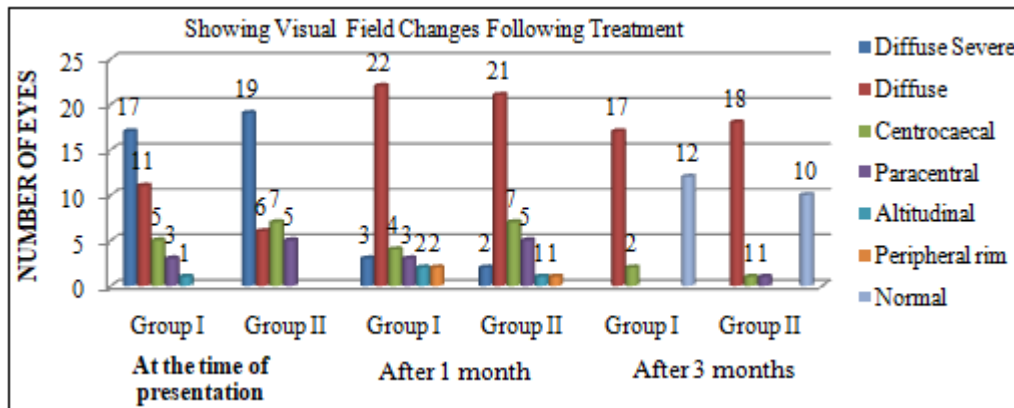


Table 8: Visual Field Changes in Eyes at Presentation and on Subsequent Follow Ups

Type of Defect	At the Time of Presentation		Day3		Day 7		1 Month		3 Months	
	Group I	Group II	Group I	Group II	Group I	Group II	Group I	Group II	Group I	Group II
Diffuse Severe	17	19	10	12	3	2	-	-	-	-
Diffuse Severe	11	6	17	11	22	21	22	15	17	18
Centrocaecal	5	7	5	9	4	7	4	7	2	1
Paracentral	3	5	3	4	3	5	1	4	-	1
Altitudinal	1	-	1	1	2	1	1	1		
Peripheral rim	-	-			2	1	-	2		
Normal	-	-					5	4	12	10
Total Number of Eyes	36	37	36	37	36	37	34	33	31	30
<i>p value</i>	0.672578		0.602223		0.699978		0.28184		0.97534	

Using Humphrey full threshold technique pretreatment visual fields could be charted in only 20 eyes in group I and 18 eyes in group II. Visual field defects seen in group I were diffuse defect in 10 eyes, centrocaecal scotoma in 5 eyes and paracentral scotoma in 3 eyes, whereas in group II, diffuse defect, centrocaecal scotoma and paracentral scotoma was seen in 6 eyes, 7 eyes and 5 eyes respectively. At 3 months follow up in group I, 12 (38.70%) eyes showed normal visual fields while centrocaecal scotoma persisted in 2 eyes

and diffuse constriction of the visual field in 17 out of 31 affected eyes. At 3 months follow up in group II, 10 (33.33%) of eyes had normal visual fields. centrocaecal scotoma persisted in 1 eyes, paracentral scotoma in 1 eye and diffuse constriction of the visual field in 18 out of 30 affected eyes. No fellow eye defect in visual field noted in any patient.



All of the investigations for infection including VDRL, serological tests for toxoplasmosis and anaerobic cultures were negative in all the patients in both the groups. Chest X-rays were either normal or had nonspecific changes. The X-rays of the paranasal sinuses did not show evidence of sinusitis. All other eyes investigations were within normal limits.

On administration of pulse steroid five patient in group I and seven patient in group II complained of generalized weakness. Gastric irritation occurred in four patient of group I and three patients of group II. Sleep disturbances occurred in one patient of group I and two patients of group II. Weight gain was noted in one patient of group II.

4. Discussion

This hospital based prospective study compared the outcome of visual parameters and side effects after treatment with intravenous dexamethasone as compared to intravenous methylprednisolone in cases of optic neuritis.

Out of 30 patients (36 eyes) in group I, 4 patients (5 eyes) were lost to follow up. In group II, out of 30 patients (37 eyes), 5 patients (7 eyes) were lost to follow up. In the present study age of the patients in group I ranged from 18 to 60 years and 17 to 60 years in group II. In our study the mean age group was 31.57 ± 10.31 years in group I and 31.93 ± 10.71 years in group II.

Table shows the age group observed by different authors

Author	Year	Mean Age Or Age Distribution
Tandon R. et al [8]	2006	31.02 ± 13.41 years
Mehrotra A. et al [9]	2007	Dexamethasone group: 31.2 ± 10.1 years. Methylprednisolone group: 26.6 ± 11.5 years
Panjiyar et al [10]	2015	Dexamethasone group: 30.07 ± 12.76 years. Methylprednisolone group: 31.97 ± 14.05 years
Present Study	2016 - 2017	Dexamethasone group: 31.57 ± 10.31 years. Methylprednisolone group: 31.93 ± 10.71 years

Regarding the age incidence, the age group of present study is quite in agreement with other authors. In the present study we had female preponderance with 56.67% (17) female, 43.33% (13) males in group I and 53.3% (16) females, 46.6% (14) males in group II.

Table shows sex incidence observed by different authors

Author	Year	Females (%)	Males (%)
Tandon R. et al	2006	25	75
Mehrotra A. et al	2007	Dexamethasone group: 45.45 Methylprednisolone group: 40.0	Dexamethasone group: 54.54 Methylprednisolone group: 60.0
Panjiyar et al	2015	63.33	36.6
Present Study	2016 - 2017	Dexamethasone group: 56.67 Methylprednisolone group: 53.3	Dexamethasone group: 43.33 Methylprednisolone group: 46.6

Similarly **Ismail S et al** in their studies had found female preponderance¹¹. The findings of the present study resembles that of **Bista S et al**¹², **Ismail S et al**¹¹, **Panjiyar et al**¹⁰

Unilateral optic neuritis, 78.3% (n=47) dominated our study group. Tandon R. et al⁸, Mehrotra A. et al⁹, Panjiyar et al¹⁰ in their studies found unilateral cases to be around 75%, 76.9%, 63.3%.

Studies done by **Bee et al**, **Lin et al**, **Chang et al** in Taiwan showed unilateral: bilateral to be 22: 5, 71: 38, 30: 13 respectively¹³⁻¹⁵. The findings of the present study is quite in agreement with other authors.

All the patients in both the groups presented with sudden diminution of vision. Eye pain was present in 15 (50%) cases in group I and 17 (56.67%) cases in group II. Headache was present in 2 (6.67%) in Group I and 3 (10%) in group II.

In the present study, there was significant improvement in visual acuity in all the patients enrolled for study. The p value of group I at the end of 7 days and 3 months were 0.00032 and 0.00402 respectively which was statistically significant (i.e. p < 0.05). In group II. The p value of group I at the end of 7 days and 3 months were 0.00235, 0.000369 respectively which was statistically significant (i.e. p < 0.05). While comparing the p values of group I and group II at the time of presentation, after 7 days, 1 month and 1 year, it was found to be statistically insignificant.

Hence dexamethasone and methylprednisolone have equal efficacy in the outcome of the visual acuity upto 3 months follow up. The study done by **Panjiyar et al** and **Mehrotra A. et al** (2007) in All India Institute of Medical Sciences also showed similar results with no difference in visual

acuity improvement between patients receiving intravenous dexamethasone and intravenous methylprednisolone. Similarly, a study done by **Tandon R. et al**⁸ showed significant improvement in visual acuity at the end of three months follow up. In the present study at the end of 3 months follow up 70.98% of the eyes in group I and 76.66% of the eyes in group II, had normal colour vision. There was significant improvement of colour vision in both the groups following treatment, after day seven and three months follow-up (0.000037, 0.00004 respectively in group I and 0.000328, <0.00001 respectively in group II; $p < 0.05$). While comparing the p value of group I and group at each follow-up it was found to be statistically insignificant.

A study done by **Mehrotra A. et al** (2007), which compared the efficacy of Dexamethasone with Methylprednisolone found that in group I, 81.1% and in group II, 70% of the cases had normal colour vision at 3 months follow up. In a study done by **Tandon R. et al** (2006), 75% of the cases had normal colour vision after administration of Dexamethasone at 3 months follow up period, 14.28% had partial colour deficiency and 10.72% had absolute colour deficiency. However **Panjiyar et al** (2015) in their study found that in the dexamethasone group, 95.2% of the eyes and 97.5% of the eyes in the methylprednisolone group had normal colour vision at the end of 3 months follow up.

In the present study there was significant improvement in visual field in both the groups after day seven and three months (p value 0.0039, 0.001785 respectively in group I and 0.000053, <0.00001 in group II, both statistically significant). While comparing the p-value of both the groups on subsequent follow-ups it was found to be statistically insignificant (0.672, 0.602, 0.699, 0.281, 0.975) Study done by **Panjiyar et al** (2015) had normal visual field in 80.95% of the eyes in group I i.e dexamethasone group and 82.5% of eyes in group II i.e methylprednisolone group. Another study done by **Mehrotra A. et al** (2007) showed normal visual field in 81.8% of the patients who received intravenous dexamethasone and in 90% of patients who received methylprednisolone at the end of 3 months follow up. Before treatment, all eyes had abnormal visual field in that study. **Tandon R. et al** (2006) showed normal visual fields charted by Goldmann perimeter in 75% of the eyes at the end of 3 months while persistent centrocecal and paracentral scotomas were found in 14.28% and 10.72% eyes respectively. In the same study Humphrey visual fields return to normal in 9 eyes (32.14%) out of 28 eyes, while remaining 19 eyes (67.86%) eyes had persistent diffuse defects. This is comparable with our study where Humphrey visual fields returned to normal in 12 eyes (38.70%) out of 31 affected eyes in the dexamethasone group, while the remaining 17 eyes (54.83%) had persistent diffuse defects and 2 (6.45%) eyes had centrocecal defects. In the methylprednisolone group Humphrey visual fields return to normal in 10 (33.33%) eyes out of 30 affected eyes, while the remaining 18 (60%) eyes had persistent diffuse defects and 1 (3.33%) eye had centrocecal defects and 1 (3.33%) eye had paracentral defect.

Six months follow up result in ONTT (1992) showed that all four vision test results (visual acuity, colour vision, contrast sensitivity and visual field) were highly intercorrelated at

baseline and at six months. Due to financial considerations dexamethasone can be considered as an alternative for treatment of optic neuritis in our country.

All patients were negative for serological investigations. None of the patients yielded a positive blood culture. Chest X-ray was normal or had nonspecific changes. The ONTT had concluded that laboratory investigations and CSF examination were not required routinely¹⁶. All the side-effects were of a mild nature not requiring any treatment. In the ONTT the adverse effects of treatment included insomnia, mood changes, gastritis, facial flushing and weight gain¹⁷.

5. Conclusion

The present study showed that intravenous dexamethasone and intravenous methylprednisolone therapy to be equally effective in treatment of primary typical optic neuritis as recommended by the ONTT study. Patients on dexamethasone responded well to therapy with prompt recovery of visual parameters and no serious side effects. Dexamethasone can be considered as an alternative to methylprednisolone, in cases where there are financial constraints. However broader and more elaborate studies are required to establish the efficacy and safety of intravenous dexamethasone as an alternative to intravenous methylprednisolone.

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