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Assessment of Pain, Swelling, Trismus Following Impacted Lower Third Molar Surgery, With Pre-Operative Single Dose Oral Dexamethasone: A Prospective, Randomized Double Blind Controlled Clinical Trial

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Abstract

Background: The removal of the lower impacted third molar teeth is always associated with varying degrees of inflammation that may have a social impact for the patients. To control these symptoms associated, it is necessary to provide an adequate anti-inflammatory therapy. The present study was undertaken to evaluate the therapeutic effect of pre-operative single dose of 8 mg oral Dexamethasone on pain, swelling, trismus following impacted lower third molar surgery.

Materials and Methods: This study was conducted at MGPGI puducherry. Hundred patients with bilateral mandibular molar impaction were included in the study. Patient was allocated randomly as study and control group. Study group received 8 mg oral Dexamethasone one hour prior the surgical extraction. Patients with contraindication to the use of steroids were excluded from the study. Pain, facial contour and mouth opening were measured preoperatively and at 2nd and 5th days postoperatively.

Results: On 2nd post-operative day, no statistically significant differences were noted in pain for both the groups. However, low pain scores were obtained with the use of Dexamethasone compare to placebo group. Dexamethasone group showed statistically significant reduction in swelling and trismus compared with the control group at all intervals.

Conclusion: Dexamethasone 8 mg given orally one hour preoperatively is effective in minimizing pain, swelling, and trismus after removal of impacted lower third molar teeth.

Keywords: Dexamethasone, Pain, Swelling, Trismus, Post-operative

Introduction

Tooth impaction is one of the common problem most of the people facing on. The impaction rate is higher for lower third molars when compared with other teeth. The prevalence of third molar impaction ranges from 16.7% to 68.6%. The cause of impacted lower third molar includes inadequate space in the mandible to accommodate the erupting teeth [1].

The surgical removal of mandibular third molars is one of the most common procedures in Oral and Maxillofacial field. This involves trauma to soft and bony tissue and can result in considerable pain, trismus and swelling that can arise from inflammatory response which is a direct and immediate consequence of the surgical procedure [2]. These expected sequelae influence the patient's quality of life and can cause distress to the patient in the immediate post-operative period. Although inflammatory response is

good for healing, it can cause significant distress. So it is essential to regulate the process of inflammation. Many clinicians have proposed several methods to control the immediate inflammatory responses that include different surgical closure techniques with or without incorporation of drains [3], use of drugs such as analgesics, corticosteroids antibiotics etc [4].

In the early 1950s, when Spics et al. and Horton started administrating corticosteroid to prevent inflammation in oral surgery that significantly alters the inflammation [5]. Using steroids for longer periods have few complications, but in dental surgeries the dosage are less and for short duration, hence the chance of adverse effect is very less.

Dexamethasone is a synthetic adrenocortical steroid that has been used extensively in Oral and Maxillofacial surgery due to its high potency and long half-life. It can be delivered by either oral, intravenous, intramuscular in masseter, gluteal or deltoid region, submucosal injection, endo alveolar powder. Effect of this drug on pain, swelling and trismus was found to be vary according to the route of administration [6] and when given preoperatively or perioperatively than post-operative [7]. So the present study involves randomized use of a single dose of 8 mg Dexamethasone given orally one hour preoperatively for the surgical extraction of impacted lower third molars under local anesthesia. The efficacy of this procedure in controlling typical post-operative complications (pain, swelling, and trismus) was evaluated.

Materials and Methods

The study was conducted in the Department of Oral and Maxillofacial Surgery, MGPGI, Puducherry between May 2016 and October 2017. 100 patients were selected from the outpatient department of the institute. Subjects undergoing surgical removal of bilateral impacted third molar teeth and who was willing to give informed consent were included in the study and were randomly assigned either to receive (group A) or not (group B) 8 mg Dexamethasone (oral route) one hour preoperatively. Inclusion criteria included patients having bilateral mandibular third molar with Pell and Gregory's class II position B impaction, Equivalent degree of surgical difficulty (Pederson's Index) comparing one side with the other. Patients' age 18 to 35 years. Patients contraindication to the use of corticosteroids with associated medical condition like hypertensive, diabetics, GIT ulcer, acute/chronic infections, renal insufficiency, Patients taking antibiotics or anti-inflammatory drugs within 2 weeks of the study, Patients having pericoronitis or infections at the time of operation were excluded from

the study. Approval of Research and Ethics committee of the institution was obtained to conduct this study.

In this split mouth study, one hour before the surgery, patient was randomized to either one of the group. The study group received a single dose of oral 8 mg Dexamethasone, while the control received an oral placebo drug. Both the patients and the surgeon were blinded to the drug. A third person, staff nurse of our department, who was not involved in the study, was made in charge of dispensing the drugs randomly and maintaining the record of drug dispensed to each patient. This record was not revealed to the investigator till the completion of study and obtaining results. Pain, facial contour and mouth opening were measured preoperatively.

The surgical procedure was performed under local anaesthesia using 2% Lignocaine hydrochloride containing 1:80,000 adrenaline. Standard inferior alveolar nerve block and long buccal nerve block of surgical site was given. Using standard ward's mucoperiosteal flap, bone guttering was done with low speed straight hand piece and no.703 bur. The wound closure was done using 3-0 Black braided silk sutures. Standard post-operative instructions were given to the patients.

The second surgical procedure was performed on the contra lateral side, with an interval of 2 weeks between procedures.

Severity of pain perception was assessed using a 10 cm Visual Analogue Scale. Accordingly, '0' was recorded as no pain and '10' as worst pain (Figure 1).

Figure 1: Visual analogue scale.

Swelling was assessed clinically by making the patient sit upright and measuring the distance between 5 fixed points on surgical side of the face using tape and finding the average. The measurements were made in closed mouth position. The fixed points were, A: the most posterior point at the midline on the tragus, B: lateral canthus of the eye,

C: the most lateral point on the corner of the mouth, D: soft tissue pogonion which is the most prominent point at the midline on the chin and E: most inferior point on angle of the mandible. The 3 lines were AD (Figure 2a), AC (Figure 2b) and BE (Figure 2c).

Figure 2: Assessment of swelling.

Trismus was assessed by measuring the mouth opening. It was evaluated by measuring the inter-incisal distance at maximum mouth opening using a Vernier calliper (Figure 3).

Figure 3: The inter-incisal distance at maximum mouth opening using a vernier calliper.

Routine follow up were given on post-operative days 2 and 5 to access all the above parameters.

Results

Among 100 patients of bilateral mandibular impacted molars, who met the inclusion criteria, 16 were males and 34 were females. The age of the patients ranged from 18

to 35 years, with the average age being 25 years. Total of 100 surgical extractions were done, 50 in Dexamethasone group and 50 in placebo group.

At follow-up, no patients developed wound infection or serious post-operative complications and any drug side effect.

All the patients were followed up on the 2nd and 5th post-operative days. Statistical analysis was done by SPSS 20 software, were mean values with standard deviation and one-way analysis of variance test (ANOVA) and paired 't' test was used to compare the variables under study (Table 1).

As shown in table 2, no statistically significant difference was noted in pain during the 2nd post-operative day for both the groups. However, low pain scores were obtained with the use of Dexamethasone compare to placebo group. Statistically significant differences in all phases of swelling was shown in Dexamethasone group ($P = 0.013, 0.005, 0.069$, respectively). Mouth opening measurements (millimetre) was converted in percentage for both the groups Mouth opening was significantly improved following surgery in which Dexamethasone was prescribed.

Swelling was not significantly reduced in all phases in placebo group. While comparing both the groups there is a significant difference in post-operative pain and trismus in 2nd and 5th day ($p < 0.05$) (Table 3).

Discussion

Surgical extraction of lower impacted third molar results in inflammation, which is responsible for neutralizing and removing the antigens and the remains of damaged tissue [6]. Although inflammatory response is necessary for healing to occur, often excessive inflammation can affect the quality of life of the patient. To minimise such discomfort, methods like cryotherapy, ultrasound bone surgery [8]. Use of drain, electro-acupuncture [9], primary and secondary closure of surgical wound and various drugs were used. Tiwana et al. reported that the administration of corticosteroids before third molar surgery offers a beneficial effect on health-related quality of life [10]. There are different types and forms of corticosteroids available. Also different routes of administration were followed. But currently there is no well-accepted standard dosage regimen, time and route of administration by Maxillofacial Surgeons [11]. Herrera-Briones et al. concluded in their systematic review that more comparative studies with different corticosteroids are needed in order to establish

Table 1: Data on study participants.

SI No	Name	Age/Sex	Surgery	Pre Operative			Post Operative					
				PAIN	FC (CM)	MO (MM)	2nd day PAIN	2nd day-FC	2nd day-MO	5th day PAIN	5th day-FC	5th day-MO
1	Vaitegi	29/F	DEXA	2	11.5	45	2	11.7	35	1	11.5	45
			PLACEBO	2	11.4	45	4	11.5	30	2	11.4	40
2	Shalini	30/F	DEXA	0	12.3	60	2	12	48	6	12.3	47
			PLACEBO	2	12.4	60	2	12.7	30	0	12.4	49
3	Raj Kumar	23/M	PLACEBO	0	10.9	55	2	11.7	46	2	11.6	50
			DEXA	2	11.4	60	4	11.4	50	0	11.4	55
4	Priya	22/F	DEXA	0	11.2	40	2	11.2	40	0	11.2	40
			PLACEBO	2	11.1	40	4	11.6	35	2	11.2	37
5	Kanmani	21/F	PLACEBO	2	12.1	37	0	12	35	0	12	33
			DEXA	0	12.1	42	4	12.2	20	4	12.3	22
6	Payaniammal	30/F	PLACEBO	2	11.6	33	2	11.7	30	0	11.5	32
			DEXA	2	11.7	30	0	11.6	15	0	11.7	27
7	Baskaran	25/M	PLACEBO	2	12.9	60	2	13.1	30	0	12.9	35
			DEXA	2	12.9	60	2	12.7	50	0	12.9	55
8	Manikandan	32/M	PLACEBO	2	13.2	45	4	12.8	30	6	13.6	30
			DEXA	2	13.2	40	2	13.2	35	0	13.2	39
9	Matheswari	27/F	DEXA	2	12.3	41	2	11.9	35	0	11.9	39
			PLACEBO	2	12.9	40	2	12.5	40	0	12.8	42
10	Sathya	21/M	PLACEBO	2	12.9	65	0	12.9	30	0	12.8	32
			DEXA	2	13.5	60	2	13.3	40	2	13.3	48
11	Lenin	30/M	DEXA	4	12.4	40	2	12.9	25	2	12.7	30
			PLACEBO	2	12.5	40	0	12.5	30	0	12.5	40
12	Thangadurai	25/M	PLACEBO	2	12.5	63	2	12.6	40	0	12.8	53
			DEXA	2	12.6	60	0	12.6	55	0	12.6	58
13	Patchiammal	35/F	DEXA	2	11.3	40	2	12	30	0	11.3	35
			PLACEBO	2	11.8	40	4	12.1	20	2	11.8	25
14	Ranjitha	24/F	PLACEBO	2	11.3	45	2	11.5	30	0	11.2	30
			DEXA	2	11.2	40	2	11	35	0	11.2	38
15	Nithya	30/F	PLACEBO	2	11.8	50	4	12.6	15	2	12.5	20
			DEXA	2	11.9	50	2	11.9	45	2	11.8	47
16	Kalairasi	27/F	PLACEBO	0	11.8	48	0	12.1	32	0	11.8	45
			DEXA	2	12	50	2	12	40	0	12	49
17	Vijaya	21/F	PLACEBO	2	12.3	38	0	12.3	24	0	12.2	30
			DEXA	2	11.9	46	0	11.8	30	0	11.7	40
18	Veng	25/F	DEXA	2	12.1	63	2	11.9	40	0	12.1	45
			PLACEBO	2	12.2	60	4	12.6	40	2	12.3	55
19	Seetha	18/F	PLACEBO	2	11.2	35	2	11.7	20	0	11.2	30
			DEXA	2	11.6	40	2	11	35	2	11.2	38
20	Anitha	30/F	PLACEBO	2	11.7	50	4	11.9	20	2	11.7	45
			DEXA	2	12.1	50	2	11.9	30	0	12	40
21	Krishna	30/M	DEXA	2	12.6	40	0	12.7	30	0	12.5	35
			PLACEBO	2	12.6	40	4	13	35	2	12.8	30
22	Gomathi	30/F	PLACEBO	2	12.6	50	0	12.8	25	0	12.5	40
			DEXA	2	12.8	50	2	12.6	40	0	12.8	45
23	Somanath	19/M	DEXA	2	12.4	53	0	12.4	35	0	12.2	50
			PLACEBO	2	12.4	53	4	12.6	20	2	12.6	24
24	Jayalekshmi	25/F	DEXA	2	12.4	38	2	12.3	28	0	12.4	35
			PLACEBO	2	12.6	40	4	13	20	2	12.8	30
25	Sankari	27/F	DEXA	2	11.1	45	2	11.1	23	0	11.1	30
			PLACEBO	2	11	45	2	11.5	45	0	11.1	40
26	Subramani	30/M	DEXA	2	12.4	47	0	12.2	40	0	12.4	45
			PLACEBO	2	12.4	47	4	12.6	22	2	12.6	30
27	Vijayasri	23/F	DEXA	2	11.8	43	4	11.7	25	2	11.7	40
			PLACEBO	2	11.7	45	4	12	20	2	11.8	40
28	Gulab Nabi	29/M	DEXA	2	11.5	48	0	11.6	43	0	11.6	44
			PLACEBO	2	12.1	45	0	12.2	43	0	12.1	43

29	Susanth	27/M	DEXA	2	12.4	53	0	12.5	45	0	12.2	46
			PLACEBO	2	12.4	45	0	12.3	40	0	12.4	42
30	Sathish	30/M	PLACEBO	2	12.4	30	0	12.8	24	0	12.6	35
			DEXA	2	12.5	30	2	12.4	25	0	12.4	25
31	Kumaresan	24/M	DEXA	2	12.6	56	0	13.2	20	0	13.1	45
			PLACEBO	2	12.8	53	0	13.2	30	0	12.9	45
32	Priyadarsini	24/F	PLACEBO	2	11.8	44	0	11.2	26	0	11.2	35
			DEXA	2	11.3	40	4	11.6	20	2	11.2	30
33	Riswana	18/F	DEXA	2	11.2	33	2	12	24	2	12.5	30
			PLACEBO	2	11.8	33	4	12.2	20	2	11.8	28
34	Vengatraman	30/F	DEXA	2	11.9	45	0	11.7	33	0	11.8	40
			PLACEBO	2	11.8	45	2	11.6	20	2	12	35
35	Manimegali	23/F	DEXA	2	12	45	4	13.1	35	2	12.2	37
			PLACEBO	2	12.3	35	2	12.7	25	2	11.7	30
36	Jansi Rani	22/F	PLACEBO	2	11.9	22	0	12.8	16	0	12.1	20
			DEXA	2	12.1	38	2	13.2	30	0	12.3	35
37	Priyadarsni	18/F	DEXA	2	12.2	45	4	11.9	23	2	11.2	40
			PLACEBO	2	11.2	35	4	12.5	30	2	11.2	32
38	Krithika	22/F	DEXA	2	11.6	43	0	12.9	37	0	11.7	40
			PLACEBO	2	11.7	37	4	13.3	30	2	12	35
39	Sasi	30/F	DEXA	2	12.4	27	2	12.9	20	0	12.5	22
			PLACEBO	4	10.9	25	4	12.5	20	2	12.8	20
40	Sukkiran	30/M	DEXA	2	11.4	58	2	12.6	30	0	12.5	35
			PLACEBO	2	11.2	60	4	12.6	30	2	12.8	50
41	Manjula	22/F	DEXA	2	11.1	33	0	12	15	0	12.2	30
			PLACEBO	2	12.1	30	4	12.1	20	2	12.6	25
42	Dinesh	22/M	DEXA	2	12.1	54	0	11.5	38	0	12.4	38
			PLACEBO	2	11.6	38	4	11	25	2	12.4	28
43	Shamsunder	21/M	PLACEBO	2	11.7	63	0	12.6	36	0	13.1	44
			DEXA	2	12.9	65	2	11.9	54	2	12.9	60
44	Pattu	30/F	DEXA	2	12.9	45	2	12.1	35	2	11.2	40
			PLACEBO	2	13.2	45	4	12	34	2	11.2	38
45	Navatha	30/F	DEXA	2	13.2	36	2	12.3	30	2	12.5	35
			PLACEBO	2	12.3	36	2	11.8	25	2	11.8	30
46	Srinivasan	26/M	DEXA	2	12.9	55	0	13.3	50	0	11.8	53
			PLACEBO	2	12.9	55	4	12.9	35	4	12	40
47	Dhivya	23/F	DEXA	2	13.5	30	0	12.5	20	0	12.2	28
			PLACEBO	2	11.2	30	4	12.6	25	2	11.7	30
48	Parveen	28/F	PLACEBO	2	11.6	42	1	12.6	20	0	12.1	30
			DEXA	2	11.7	45	4	12	30	2	12.3	35
49	Karthika	23/F	DEXA	2	12.4	40	0	12.1	20	0	11.2	36
			PLACEBO	2	10.9	40	4	11.5	37	2	12.8	39
50	Deepika	21/F	DEXA	2	11.4	40	0	11	35	0	12.5	38
			PLACEBO	2	12.2	40	4	12.6	30	2	12.8	35

the most effective regimen to control the discomfort after third molar extraction [12]. King et al. reported that the potential adverse effects with the use of corticosteroids depend on the intensity and duration of therapy, as the short period causes few adverse effects [13]. So a safest duration and dosage of the drug was used in this study.

Dexamethasone has anti-inflammatory properties, which are probably related to their action on microvasculature as well as to cellular effects. The half-life of Dexamethasone is 36-72 hours. Vegas Bustamante et al. have suggested that the selected corticosteroid should have scant mineralocorticoid effects and great biological activity. Dexamethasone meets these requirements, since

it has no mineralocorticoid activity and is 25 times more potent than hydrocortisone [14].

To be effective, the drug should be more than the cortisol released normally by the body. Due to this reason, in the present study 8 mg of Dexamethasone was used. About the duration of the drug, a single dose one hour before the third molar surgery was chosen, because no literature has been found about the complications from the use of a single dose of corticosteroid [15]. The rationale behind pre emptive administration is that corticosteroids should be administered prior to the onset of inflammatory process [16]. Laureano Filho et al. evaluated the effect of 4 mg and 8 mg of Dexamethasone administered following third molar

surgery and found that the dose of 8 mg administered proved more effective, providing a greater reduction in post-operative edema and trismus in comparison to that achieved with 4 mg, but with no effectiveness in controlling pain [17]. Alcantara et al. compared the oral administration of 8 mg Dexamethasone with 40 mg Methylprednisolone. The study showed a better performance on edema for Dexamethasone, at all times evaluated. The authors explained that Dexamethasone achieved better performance due to its long duration of action and greater potency as compared to methylprednisolone [18].

To eliminate variations in the inflammatory response resulting from individual differences, the split-mouth design was employed. Also same position or levels of impacted teeth were selected with the help of a radiograph. Thus Pell and Gregory's classification was used in the study.

Studies show that whatever be the route of administration, Dexamethasone achieves similar results in the post-operative periods [19]. The oral route is a convenient, secure and inexpensive administration route for most patients. Dexamethasone in particular appears to decrease pain after surgery. But the real contribution of Dexamethasone to pain control is still not fully understood. Although some reduction of post-operative pain generally accompanies a reduction of edema, steroids alone do not have a clinically significant analgesic effect. Dionne et al. found that Dexamethasone 4 mg administered intravenously and orally 1 hr before and 12 hrs after third molar extraction, respectively, led to a reduction in the thromboxane TXB₂; however, the reduction in the amount of the prostaglandin PGE₂, which is the main mediator responsible for the response to peripheral pain, was not controlled properly [20]. In the present study, the patients were instructed to use Ibuprofen 400 mg in the post-operative period for 3 days.

Bauer et al. evaluated the efficacy of Ibuprofen and Dexamethasone combination in patients undergoing surgery for impacted tooth removal. Patients consumed fewer rescue analgesics in the group using the Dexamethasone and ibuprofen association ($P < 0.05$) and felt more comfortable after surgery [21]. In the present study, patients scored less pain at all post-operative evaluation times following surgeries in which Dexamethasone was used compared to group B. The results of the current study are in agreement with those of studies available in the literature.

Post-surgical facial edema is hard to quantify accurately,

because it is the measurement of an irregular, convex surface and can manifest internally as well as externally. Over the years, numerous researchers tried various measurement techniques in an effort to objectively measure edema [22]. In order to use a more sensitive method to measure swelling, in this study, facial edema was evaluated by measuring the distance between the predetermined points (tragus, oral commissural, external canthus, pogonion and gonion angle) using a skin marker—was chosen because it is a valid, easy, and inexpensive method. Other methods for measuring edema can be CT scan, photographs, calipers, malleable metal rods, palpation and subjective clinical observation. In this study on comparing both the groups, edema significantly reduces from 2nd and 5th day postoperatively in group I, when maximum facial swelling is expected. Vegas-Bustamante et al. stated from his study that independent t-test found a mean reduction in mouth opening of approximately 10.07 mm in the study group and 14.78 mm in the control group on the second post-operative day. The enhanced effect of steroids on mouth opening may be observed clinically [14]. In the present study, the mean reduction in mouth opening between the post-operative days 2nd and 5th, in group A, shows a clinically significant difference in the inter incisal distance. However, whether this is as a result of the direct effect of the steroid or is a consequence of reduced swelling or pain needs to be verified. Fluid transudation within the muscles of mastication adjacent to the surgical site may lead to muscle stiffness. Trismus may also occur as an effect of muscle pain, either from the masseter muscle (due to its proximity to surgical site) or the lateral pterygoid muscle (due to prolonged mouth opening during surgery or stressed during extraction) [15].

One of the limitation of the study was the fact that ibuprofen was used for controlling post-operative pain. It has to be noted that Ibuprofen (an NSAID) prescribed postoperatively have been reported to reduce inflammation and in this case, would have either augmented and skewed the results relative to corticosteroid use. Jarrah et al. had proved the synergistic effect of corticosteroids (Dexamethasone) with an NSAID (Ibuprofen) in controlling post-operative pain and trismus, as opposed to corticosteroid alone in his study, which supports to reduce the confounding factor in the present study [16].

Conclusion

From our study, we conclude that the administration of single dose of 8 mg Dexamethasone orally one hour preoperatively is effective in reduction of post-operative pain, swelling and trismus following impacted lower third

Table 2: Paired comparison of Pain, facial contour and trismus in different time periods in dexamethasone group.

Dexamethasone	Groups	N	Mean	SD	Paired t	p value
Pain	Pre	50	1.92	0.56	1.478	0.146
	2nd day	50	1.6	1.34		
	Pre	50	1.92	0.56	5.346	0
	5th day	50	0.74	1.25		
	2nd day	50	1.6	1.34	4.759	0
	5th day	50	0.74	1.25		
Facial contours	Pre	50	12.38	0.5	2.566	0.013
	2nd day	50	12.17	0.61		
	Pre	50	12.38	0.5	2.92	0.005
	5th day	50	12.11	0.63		
	2nd day	50	12.17	0.61	0.573	0.069
	5th day	50	12.11	0.63		
Trismus	Pre	50	33.32	10.1	8.635	0
	2nd day	50	39.58	8.75		
	Pre	50	33.32	10.1	12.091	0
	5th day	50	45.54	9.36		
	2nd day	50	39.58	8.75	7.988	0
	5th day	50	45.54	9.36		

Table 3: Paired comparison of pain, facial contour and trismus in different time period in placebo group.

Placebo	Groups	N	Mean	SD	Paired	p value
Pain	Pre	50	1.96	0.49	1.964	0.055
	2nd day	50	2.42	1.69		
	Pre	50	1.96	0.49	3.841	0
	5th day	50	1.24	1.27		
	2nd day	50	2.42	1.69	7.849	0
	5th day	50	1.24	1.27		
Facial contours	Pre	50	12.15	0.62	0.426	0.672
	2nd day	50	12.11	0.63		
	Pre	50	12.15	0.62	1.008	0.318
	5th day	50	12.07	0.58		
	2nd day	50	12.11	0.63	0.529	0.599
	5th day	50	12.07	0.58		
Trismus	Pre	50	28.7	7.78	7.486	0
	2nd day	50	35.52	8.42		
	Pre	50	28.7	7.78	10.742	0
	5th day	50	43.94	10.11		
	2nd day	50	35.52	8.42	7.468	0
	5th day	50	43.94	10.11		

molar surgery. Variables under the study were measured either subjectively or objectively. To overcome the limitation of this, further prospective long term studies are needed to quantify the changes in the levels of chemical mediators of inflammation after the administration of corticosteroids in order to obtain more reliable findings and minimize these undesirable effects among patients.

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