



Comparison between Sodium Diclofenac 0.1 % and Dexamethasone 0.1 % Eyedrops in Cell and Flare Inflammation Post Phacoemulsification

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Abstract

Introduction: Cataract is an eye disorder in the form of cloudiness of the lens caused by hydration of the lens fluid. In Indonesia, the leading cause of blindness is cataract, especially in North Sumatra. Cataract surgery with phacoemulsification technique can cause inflammation. As respond to inflammation, 0.1% dexamethasone eyedrops and 0.1% diclofenac sodium eyedrops was given. This study was conducted to determine the effectiveness of suppressing inflammation between 0.1% dexamethasone and 0.1% diclofenac sodium eyedrops after phacoemulsification cataract surgery.

Methods: This study is an experimental study with a double-blind design at General Hospital of Sumatera Utara and Medan Baru Eye Centre with senile cataract patients as the sample. Patients with inflammation response such as cell and flare on the first day after phacoemulsification cataract surgery was included as the samples if the patients fulfilled inclusion criteria and not included in exclusion criteria. Cell and flare examination was done in day one, three, seven and fourteen after the given eyedrops. Data collected was then analyzed using T-paired test with significance level of $p < 0.005$.

Results: This study found significant difference between dexamethasone eyedrops and diclofenac sodium eyedrops in day one ($p=0.004$), in day three ($p=0.035$), and in day seven ($p=0.005$). In day fourteen, no significant difference was found between dexamethasone eyedrops and diclofenac sodium eyedrops ($p=0.119$).

Conclusion: Diclofenac sodium eye drops have a better anti-inflammatory effect compared to dexamethasone eyedrops in reducing the inflammatory reaction of cell and flare in the camera oculi anterior with patients after phacoemulsification cataract surgery in General Hospital of Sumatera Utara and Medan Baru Eye Centre.

Keywords: Cell And Flare, Diclofenac Sodium, Phacoemulsification

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INTRODUCTION

Cataract is an eye disorder in the form of cloudiness of the lens caused by hydration of the lens fluid. Cataract comes from the Greek word "Katarrhakies", which means vision being covered by a waterfall. Cataract is a condition in which the eye lens that is normally clear becomes cloudy. When the eye's lens loses its clearness or clarity, the vision will become cloudy or cannot see at all. Cataracts occur slowly so that the patient's vision will be gradually disturbed. Cataracts can also occur at all ages, both young and old, due to the degeneration process.¹

Cataracts cause blindness in about 20 million people in the world. It accounts for an increase in the number of cataract surgeries. The number of cataract operations per 100,000 population per year, known as the Cataract Surgical Rate (CSR), is used as an indicator to assess efforts to eradicate blindness due to cataracts. In developed countries (North America, Western Europe, Australia and New Zealand), CSR is more than 4000, of which Australia is the highest in the world, reaching 6500. In Africa and China, CSR is less than 500. In Central and South America, Eastern Europe and the Middle East, CSR is less than 1000. In India, more than 4000. Blindness due to cataracts (<3/60) is rare in countries with CSR of more than 4000, except India, where the prevalence of cataracts is very high.²

The prevalence of blindness in Indonesia reached 1.5% of the total population in Indonesia, according to the survey results in 2016. Based on this number, cataract is the main cause of blindness in Indonesia with a percentage of 0.78%. The population aged 30 years and over in North Sumatra diagnosed by health workers and stated cataract was 1.7%, while the population who experienced cataract symptoms was 9.7%. The prevalence of cataracts in North Sumatra in 2013 was 1.4%.³

Surgery is still the only therapy for cataracts, one of which is phacoemulsification. Cataract surgery is one of the most frequently performed surgeries globally and has the highest success rate. Phacoemulsification is the most common cataract surgery procedure performed today. With recent developments in phacoemulsification management, most patients can have good visual outcomes.⁴

The most common complication after cataract surgery is inflammation of the eye. Inflammation that occurs after cataract surgery can be normal due to manipulation of the iris, lysis of the zonules, and irrigation of the eye's anterior chamber during surgery. One of the signs of inflammation is the formation of cell and flare. Anti-inflammatory drugs can accelerate repair and reduce the discomfort felt by patients after surgery. In theory, any anti-inflammatory agent that blocks inflammatory mediators can be used to control postoperative inflammation. Non-Steroid Anti-Inflammatory Drugs (NSAIDs) and corticosteroids are often used to prevent and reduce inflammation after cataract surgery.⁵

Corticosteroids have long been known as an effective drug to treat inflammation after phacoemulsification cataract surgery. But behind that, corticosteroids can also have unwanted side effects such as steroid-induced glaucoma, steroid-induced uveitis, prolonged wound healing, and decreased immunity to infection. While NSAIDs are commonly used because of their anti-inflammatory, antipyretic and anti-pain properties. Several studies also reported the use of NSAIDs to prevent and treat post-phacoemulsification inflammation.^{5,6} Therefore, the researcher was interested in investigating the study with title of "Comparison of Cell and Flare Number in Post-Phacoemulsification Inflammation After Administration of 0.1% Diclofenac Sodium and 0.1% Dexamethasone Eye Drops".

METHODS

This experimental study was conducted with a double-blind design at General Hospital of Sumatera Utara and Medan Baru Eye Centre. The researcher himself conducted this research and performed as the operator of the phacoemulsification procedure and the

examiner of cell and flare of patients. Samples of this study were senile cataract patients who experienced inflammation after phacoemulsification surgery from March 2019 until the number of samples was met.

In the 2-month sampling period from March 2019 to April 2019, 58 patients met the sample criteria, consisting of 29 male patients (50%) and 29 female patients (50%). The research sample criteria were allocated into inclusion and exclusion criteria. The inclusion criteria of this study were senile cataract patients who experienced inflammation of the eye after undergoing surgery performed by the ophthalmologist using the phacoemulsification technique at General Hospital of Sumatera Utara and Medan Baru Eye Centre, without intra-surgical complications, did not suffer and had no history of glaucoma, uveitis, corneal opacities and other anterior segment disorders, as well as uncontrolled diabetes mellitus and hypertension, not being treated with systemic/local steroid/non-steroidal anti-inflammatory drugs. Exclusion criteria in this study were dense corneal opacification (Descemet fold) complications, hypersensitivity or allergic reactions or allergies to the drugs used, and did not compliance with the follow-up rules (H+1, H+3, H+7 and H+14).

Treatment with anti-inflammatory eye drops (drug A and Drug B) was started on the first postoperative day after examination of inflammatory cells in the anterior chamber of the eye. The therapy was accompanied by neomycin-polymyxin B antibiotic eye drops with the following conditions:

- First, it was given anti-inflammatory eye drops (drug A or drug B) as many as one drop, respectively.
- The second drug (neomycin-polymyxin B eye drops) was administered after an interval of 15 minutes later as much as one drop.
- Both drugs were given at a dose of 4 times a day, namely every 6 hours on the first day, then the next examination was carried out on the third day, seventh and fourteenth day after phacoemulsification and the cell and flare defects in the eye's anterior chamber was recorded. The data would then be collected and displayed in tables and graphs, tested with the T-paired test using SPSS Statistics version 26.0.

RESULTS

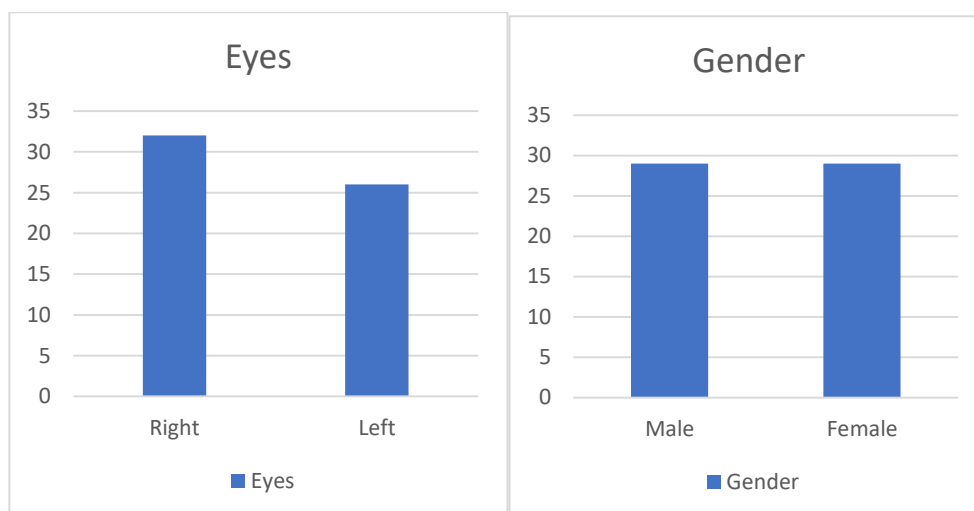
The distribution of patients based on age group, gender, and operated eye can be seen in the following table:

Table 1. Patients Distribution Based on Age Group, Gender, and Operated Eyes

Age (Years)	Male		Female		Total
	Right	Left	Right	Left	
41 - 50	3 (5.17%)	4 (6.90%)	5 (8.62%)	3 (5.17%)	15 (25.86%)
51 - 60	5 (8.62%)	9 (15.52%)	11 (18.97%)	2 (3.45%)	27 (46.56%)
> 60	2 (3.45%)	6 (10.34%)	6 (10.34%)	2 (3.45%)	16 (27.58%)
Total	10 (17.24%)	19 (32.76%)	22 (37.93%)	7 (12.07%)	58 (100%)

The youngest patient was 41 years old, and the oldest was 90 years old; the average patients' age was 59.25 + 11.14 years. Meanwhile, the largest age group was 51-60 years, namely 27 patients (46.56%). The number of male and female patients was the same, namely 29 patients.

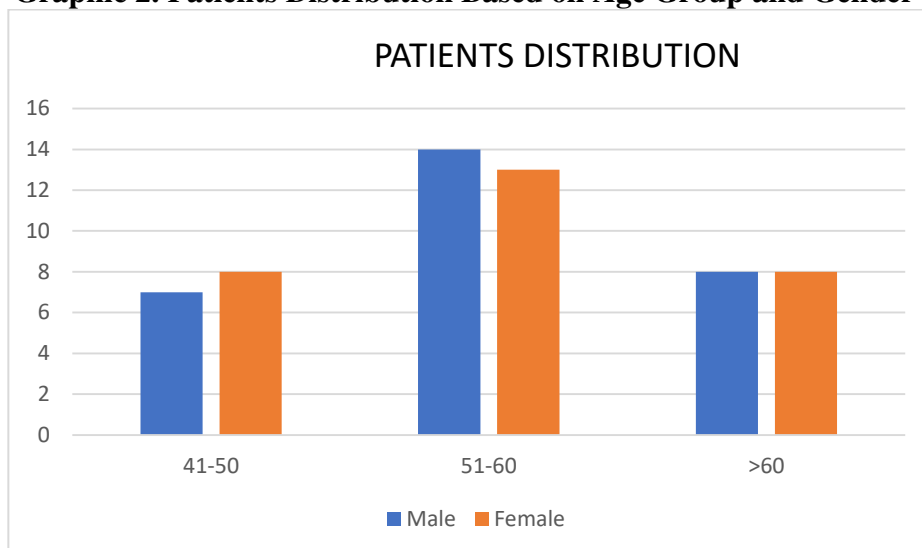
Description of the distribution of patients by sex and operated eyes can be seen in the following diagram:



Graphic 1. Patients Distribution Based on Age Group, Gender, and Operated Eyes

The distribution of patients according to age group and gender for each treatment group can be seen in the following table:

Graphic 2. Patients Distribution Based on Age Group and Gender



The distribution of patients according to the type of cataract in each treatment group can be seen in the table below:

Table 2. Patients Distribution Based on Age Group and Gender in Dexamethasone Group and Sodium Diclofenac Group

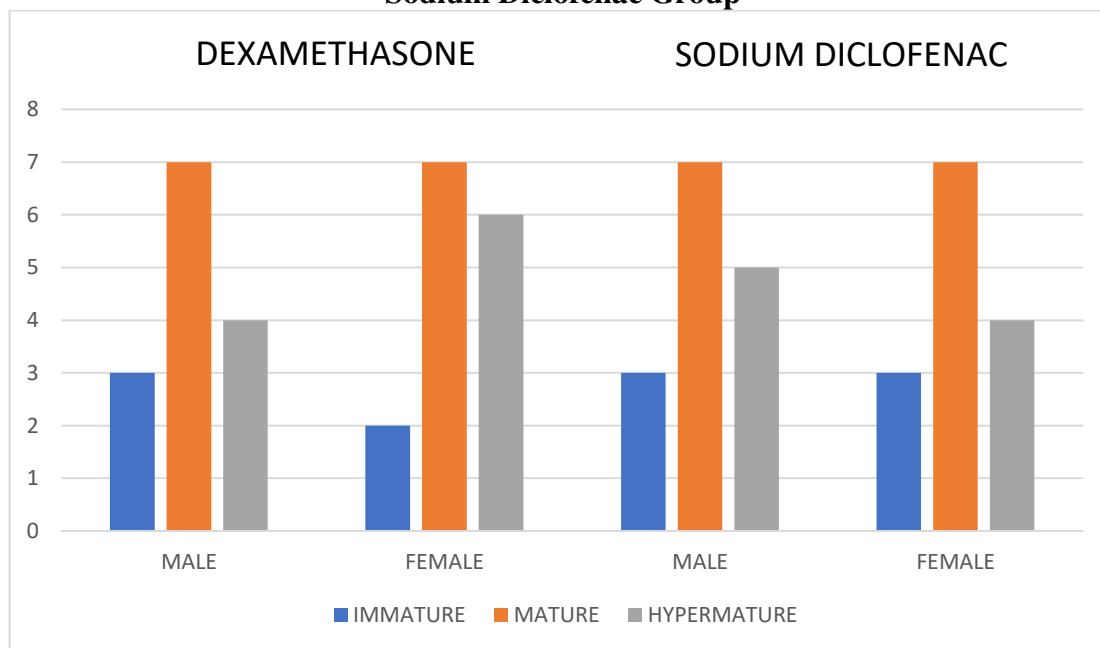
Age (Years)	Dexamethasone		Sodium Diclofenac		Total
	Male	Female	Male	Female	
41 - 50	3 (5.17%)	4 (6.90%)	4 (6.90%)	4 (6.90%)	15 (25.87%)
51 - 60	8 (13.79%)	9 (15.52%)	6 (10.34%)	4 (6.90%)	27 (46.55%)
> 60	4 (6.90%)	4 (6.90%)	4 (6.90%)	4 (6.90%)	16 (27.58%)
Total	15 (25.86%)	17 (29.31%)	14 (24.14%)	12 (20.70%)	58 (100%)

Table 3. Distribution of Patient's Cataract Type in Dexamethasone Group and Sodium Diclofenac Group

Cataract Type	Dexamethasone		Sodium Diclofenac		Total
	Male	Female	Male	Female	

Hyperature	4 (6.90%)	6 (10.34%)	5 (8.62%)	4 (6.90%)	19 (32.76%)
Mature	7 (12.07%)	7 (12.07%)	7 (12.07%)	7 (12.07%)	28 (48.28%)
Immature	3 (5.17%)	2 (3.44%)	3 (5.17%)	3 (5.17%)	11 (18.96%)
Total	14 (24.14%)	15 (25.86%)	15 (25.86%)	14 (24.14%)	58 (100%)

Graphic 3. Distribution of Patient's Cataract Type in Dexamethasone Group and Sodium Diclofenac Group



Observations of the signs of inflammatory reactions after phacoemulsification cataract surgery and intraocular lens insertion and their response to the administration of anti-inflammatory drugs for each group were carried out on each patient on the first day, third day, seventh day and fourteenth day after phacoemulsification; while the observed was cell and flare number in the eye's anterior chamber. The results of the observations as listed were analyzed by the statistical test of the T-paired test. The level of significance was set at 0.05 (5%), so it was said to be significant if $P < 0.05$ and not significant if $P \geq 0.05$.

The results of observations that show a comparison of cell and flare reduction in the anterior chamber of the two treatment groups can be seen in the following diagram table:

Table 4. Comparison between Subjects with Flare in Dexamethasone Group and Sodium Diclofenac Group

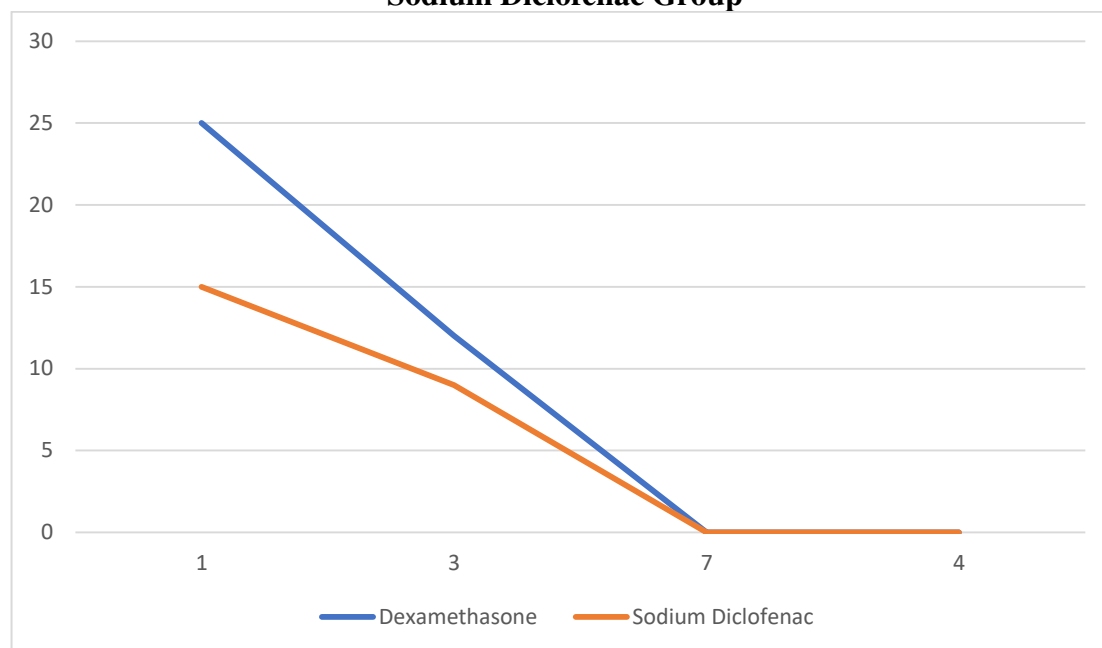
Day	Dexamethasone			Sodium Diclofenac			P	
	Patients With Flare			Patients With Flare				
	+2	+1	0	+2	+1	0		
1	25(43.10%)	4(6.90%)	0	15 (25.86%)	14 (24.14%)	0	0.004	S
3	12(20.69%)	17 (29.31%)	0	9 (15.52%)	20 (34.48%)	0	0.035	S

7	0	24 (41.38%)	5 (8.62%)	0	14 (24.14%)	15 (25.86%)	0.005	S
14	0	9 (15.52%)	20 (34.48%)	0	4 (6.90%)	25 (43.10%)	0.119	Ns

S: Significant

NS: Not Significant

Graphic 4. Comparison between Subjects with Flare +2 in Dexamethasone Group and Sodium Diclofenac Group



DISCUSSION

In this study, the assessment was carried out by assessing the presence of cell and flare in the anterior chamber, which is one of the markers of inflammation in the anterior chamber. Observations were made using a biomicroscope slit lamp with a slit width of 1 mm, an angle of 45°, magnification and maximum light intensity. The observation area was the anterior chamber of the eye in front of the pupil. Observations were made on the first, third, seventh and fourteenth days after phacoemulsification. The reduction in cell and flare count was expected due to treatment over time. In the study period of 2 months, from March 2019 to April 2019, 58 patients met the sample criteria, consisting of 29 male patients (50%) and 29 female patients (50%). The results of this study were different from the study by Zetterberg in 2014, and there were more cataract cases in women due to a decrease in the amount of estrogen.⁷

In this study, the youngest patient was 40 years old, while the oldest was 90 years old. The average age of the patients was 59.25±11.14 years. From Table 1, it can be seen that the majority of cataract patients who underwent surgery were from the age group 51-60 years, namely 46.56%. In a study conducted by Emanuela Falcinella in 2019, senile cataracts occurred at the age of 40 years, with an average age of 73.5 years. From Table 1, it can be seen that in all age groups, the number of male patients was almost the same as female patients.⁸

From Table 3, it was found that based on the type of cataract, there were far more patients with mature cataracts than immature cataracts, both in total and for each group. Assessment of cataract type was carried out based on the Lens Opacities Classification System (LOCS), where the assessment of the slit lamp was carried out to assess nuclear,

cortical and subcapsular. Overall, there were 19 patients (32.76%) with hypermature cataracts, 28 patients (48.28%) with mature cataracts, and 11 patients (18.96%) with immature cataracts. It shows that public awareness is still low of the importance of eye health examinations and low awareness of being willing to undergo surgery. The cause of this situation is because the patient has just checked himself or underwent surgery if his visual acuity has been severely impaired. Patients with cloudier cataract grading will more likely develop inflammation due to the longer duration of surgery.⁹

In this study, samples of patients post phacoemulsification were taken on the first day after phacoemulsification and showed an inflammatory reaction in the form of cell and flare in the anterior chamber of the eye. In a study conducted by Andreia in 2018 and Namrata in 2020, it was concluded that post-phacoemulsification with a longer duration of surgery showed a decrease in visual acuity, with complications such as inflammation and oedema of the cornea. NSAID therapy was given after phacoemulsification was given as a therapy for the inflammation that occurred and to prevent Cystoid Macular Edema (CME).^{10,11}

From Table 4, on the first day of administering eye drops, there was a significant difference between patients with cell and flare ($p=0.004$). Cell and flare of +2 was found in the Dexamethasone group in as many as 25 patients (43.10%), and in the Diclofenac Sodium group, there were 15 patients (25.86%). Cell and flare of +1 was found in the Dexamethasone group in as many as four patients (6.90%), and in the Diclofenac Sodium group, there were 14 patients (24.14%). The result of this study was in line with Tyson's study in 2018, where the administration of Dexamethasone reduced the rate of post-phacoemulsification inflammation.¹²

On the third day of administration of eye drops, there was a decrease in cell and flare in both groups. In the Dexamethasone group, there was a decrease in patients with cell and flare of +2 in as many as 12 patients (20.69%) and cell and flare of +1 in as many as 17 patients (29.31%). In the Diclofenac Sodium group, there was a decrease in patients with cell and flare of +2 in as many as nine patients (15.52%) and cell and flare of +1 in as many as 20 patients (34.48%). The difference between the Dexamethasone group and the Diclofenac Sodium group was significant ($p=0.035$). In a study conducted by Aleksej in 2017, patients receiving NSAID therapy post-phacoemulsification had a better development of decreasing inflammation with the time of NSAID administration.¹³

On the seventh day of administration of eye drops, both groups with cell and flare of +2 were not found, while patients with cell and flare of +1 as many as 24 patients (41.38%) in the Dexamethasone group and 14 patients (24.14%) in the Diclofenac Sodium group. There was a significant difference between the Dexamethasone and Diclofenac Sodium groups on the seventh day of eye drops ($p=0.005$). It was in accordance with Stanislaw's study in 2017, which found that cell and flare had decreased significantly on the seventh day and continued to decrease until day 11.^{14,15}

On the fourteenth day of administering eye drops, there were nine patients (15.52%) in the Dexamethasone group and 4 (6.90%) patients with cell and flare of +1 in the Diclofenac Sodium group. There was no significant difference between the Dexamethasone and Diclofenac Sodium groups ($p=0.119$). The result of this study was in line with Carlo's research in 2020, which found significant effectiveness in reducing cell and flare after administration of 0.1% Diclofenac drops on day 15.¹⁶ This research was also in line with several studies conducted by Juthani in 2017, Petheri in 2018 and Rupal in 2020, which concluded that the level of inflammation after administration of Dexamethasone and Diclofenac Sodium was effective in suppressing inflammation in the anterior chamber.^{17,18,19} A study conducted by Kumiko in 2019 found that with the administration of Dexamethasone, there was a decrease in post-cataract inflammation between the first and third postoperative days, and a significant difference occurred in 5-7 days.²⁰

CONCLUSION

From this study, we can conclude that there was a significant difference between 0.1% Diclofenac Sodium and 0.1% Dexamethasone eye drops in reducing inflammatory reactions in the form of cell and flare in the camera oculi anterior after phacoemulsification at General Hospital of Sumatera Utara and Medan Baru Eye Centre on the first, third, and seventh day for immature, mature and hyper mature cataracts.

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