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Evaluation of Side Effects of Corticosteroid Eye Drops in Post-Cataract Surgery Patients

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Abstrak

ortikosteroid merupakan hormon steroid alami pada manusia yang diproduksi oleh kelenjar korteks adrenal yang berfungsi untuk mengatasi peradangan atau gangguan autoimun pada tubuh. Pada kasus penyakit mata, obat kortikosteroid dapat berupa obat tetes mata yang banyak digunakan pada pasien pasca operasi katarak, yang berfungsi mengurangi peradangan yang terjadi pada segmen interior yang terkadang tidak diketahui penyebabnya. Tujuan penelitian ini adalah untuk mengetahui efek samping yang dapat terjadi pada penggunaan obat kortikosteroid pasca operasi katarak. Penelitian ini dilakukan dengan metode crosssectional, yang dianalisis secara deskriptif menggunakan metode universal sampling. Kegiatan ini menggunakan kriteria inklusi dan eksklusi. Metode pengambilan sampel menggunakan non-random sampling dengan metode time limited sampling yaitu mengambil seluruh data Rekam Medis Kesehatan pasien. Hasil dan pembahasan penelitian ini dilakukan di Instalasi Farmasi Klinik KMU Madura dengan melibatkan sejumlah pasien pasca operasi katarak yang menggunakan obat tetes mata kortikosteroid. Penggunaan obat tetes mata kortikosteroid berpotensi menimbulkan berbagai efek samping. Efek samping yang paling umum ditemui pada pasien adalah mata kabur, perih, mata merah, dan gatal-gatal. Obat tetes mata yang paling banyak digunakan adalah prednisolon sebesar 53,3%. Berdasarkan hasil diatas dapat digambarkan bahwa lama penggunaan obat tetes mata kortikosteroid pada pasien pasca operasi katarak di instalasi farmasi Klinik Mata KMU Madura adalah lebih dari 30 hari.

Kata Kunci: *Kortikosteroid, Operasi Katarak, Efek Samping*

Abstract

Corticosteroids are natural steroid hormones in humans produced by the adrenal cortex gland that have a function to treat inflammation or autoimmune disorders in the body. In the case of eye disease, corticosteroid drugs can take the form of eye drops that are widely used in post-cataract surgery patients, which function to reduce inflammation that occurs in the interior segment which sometimes has no apparent cause. The purpose of this study was to determine the side effects that can occur in the use of corticosteroid drugs after cataract surgery. This study was conducted with a cross-sectional method, which was analysed descriptively using the universal sampling method. This activity uses inclusion and exclusion criteria. The sampling method uses non-random sampling with the time limited sampling method, namely taking all patient's Health Medical Record data. The results and discussion of this study were conducted at the KMU Madura Clinic Pharmacy Installation involving a number of post-cataract surgery patients who used corticosteroid eye drops. The use of corticosteroid eye drops has the potential to cause various side effects. The most common side effects encountered in patients are blurring, stinging, red eyes, and itching. The most widely used eye drops were prednisolone by 53.3%. Based on the above results, it can be described that the length of use of corticosteroid eye drops in patients after cataract surgery at the KMU Madura Eye Clinic pharmacy installation is more than 30 days.

Keywords: *Corticosteroids, Cataract Surgery, Side Effects*

INTRODUCTION

Overview of Corticosteroids

Corticosteroids are anti-inflammatory drugs that can reduce the symptoms of people with certain diseases. Activities in helping the treatment process of this disease can increase the role of the cause of inflammation and provide a reduced inflammatory reaction. Corticosteroids are lipophilic and bind to glucocorticoid receptors. In corticosteroid receptors and glucocorticoids that enter the body, the main actors are to encourage the initiation and concealment of quality, encourage the development of explicit mRNAs, produce a broader creation of interactions that reduce some of the support cytokines that play a role in proteins reducing inflammatory activity in the body (3)

Corticosteroids or adrenocorticosteroids are hormones produced by the adrenal glands of the cortex, which structurally contain a steroid nucleus. The adrenal cortex synthesises two groups of steroids, namely corticosteroids (glucocorticoids and mineralocorticoids) and androgens. The work of corticosteroids is described as glucocorticoids, namely to regulate carbohydrate metabolism, while mineralocorticoids are to regulate electrolyte balance. In humans, hydrocortisone (cortisol) is the primary glucocorticoid, and aldosterone is the mineralocorticoid.

The functions of corticosteroids include metabolising macronutrients (carbohydrates, proteins and fats) and regulating the balance of fluids and electrolytes in the body. In addition, it also affects the work of the circulatory system, immune system, muscle and bone work system and nerves (Aprianto, 2016). Corticosteroids are classified based on their relative potential in Na⁺ retention, effects on carbohydrate metabolism (i.e. glycogen storage and gluconeogenesis in the liver), and anti-inflammatory effects. In general, the potential of a steroid is judged by its ability to maintain fluid balance in animals that have undergone adrenalectomy almost equal to its potential for Na⁺ retention. The potency is determined based on its effect on glucose metabolism, which is almost equivalent to its potential for anti-inflammatory effects (4).

Corticosteroid derivatives that are widely used for systemic treatment are alcoholic structures that tend to be difficult to dissolve in water, so they are made in the form of sodium salts or succinate esters in formulations, injections and solutions. The presence of a hydroxyl group at position 11 has an important role in glucocorticoid activity, while the hydroxyl group at position 21 plays a role in mineralocorticoid activity. Fluorination at position 9 increases both activities of corticosteroids. The substitution of the C-16 atom further reduces the activity of mineralocorticoids. Topical corticosteroid activity increases with esterification at positions 17 and 21. The formation of acetone cyclic at positions 16 and 17 increases topical anti-inflammatory activity without enhancing systemic glucocorticoid effects (12).

The effectiveness of corticosteroids in their use as intraocular topical preparations is influenced by their ability to penetrate the cornea as well as the rate of intraocular metabolism. To meet this, corticosteroids must bind to target cells in the intraocular. Dexamethasone was identified to bind to the nucleus portion of the conjunctiva and corneal epithelial cells. Dexamethasone has also been found to bind to keratocytes and endothelial cells of blood vessels. Dexamethasone can be distributed up to the trabecular meshwork, iris muscle, conjunctiva, choroid, retina and sclera by the route of intravenous administration (16).

Many factors can affect the bioavailability of medications given topically to the eye. The drug must be able to be absorbed by the desired target tissue so that it can provide an appropriate therapeutic effect. As many as 80% of eye drops can have drainage into the nasolacrimal canal so that they can enter the systemic. This causes eye drops to have the exact dosage as intravenous use. Drugs that enter the systemic system then follow the same metabolic flow as systemic drugs, such as breakdown by enzymes, conjugation and metabolism by the liver (Shell, 1982).

In addition, it is necessary to pay attention to the existence of drug residues because several drugs may disappear before providing therapeutic effects. The degree of ionization and P log of the drug also affects the absorption of the drug in the eye. Some drugs pass through the cornea with a passive diffusion mechanism that depends on the concentration gradient, the solubility properties of the drug, the ionized molecules and the dissociation settings of each drug. The form of the drug preparation also affects the bioavailability of the drug. Eye drops can generally be solved immediately but their bioavailability is affected by the length of contact the drug with tissues. This is different from eye ointments that are able to provide a longer time of contact with tissues. In addition, eye ointments can prevent the loss of medication by tears and maintain the amount of medication in the nasolacrimal. However, the disadvantage of eye ointment is that the patient's vision becomes blurred (7).

Corticosteroids are a class of anti-inflammatory drugs that are usually used in ocular disorders and anterior segments. When taking steroid drugs systemically or topically, periocularly, or inhalation, there will usually be an impact in the form of increased intraocular pressure, which will be seen within 3-6 weeks after use. If the increase in TIO lasts for a long time, then the adverse impact in the future is that it can cause glaucomatous optic neuropathy, which is in the form of steroid-induced glaucoma (GIS).

Overview of Cataracts

Cataracts are a disease that occurs when the lens of the eye becomes cloudy. In general, cataracts develop slowly and are not annoying at first. However, over time, cataracts will interfere with vision and make sufferers feel like they are looking at foggy windows. They will also have difficulty driving, reading, and doing daily activities. This eye disease is the leading cause of blindness worldwide that can be treated.

The mechanism of cataracts that occur in senile-type cataracts is the division and aggregation of proteins in the lens of the eye, damage to the membrane of fibrous cells, glutathione deficiency, damage due to oxidizing substances, increased calcium levels, abnormal displacement of lens epithelial cells and so on. In addition, dehydration and high levels of urea in the body also cause osmotic imbalances in the body so that there is a buildup of cyanates which will affect glutathione levels and cause cataracts. The mechanism of ion transport in the lens of the eye also affects the formation of cataracts. If the ion transport in the lens of the eye is reduced, the activity of Na^+K^+ -Adenosine Triphosphatase (ATPase) is also reduced, accelerating the onset of opacity in the lens. The most important factor in causing senile cataracts is the presence of oxidative stress in the lens of the eye so that high levels of protein are found in the lens of the eye (17).

Traumatic cataracts are formed due to injury to the lens of the eye or the presence of a foreign object that is difficult to remove from the lens, resulting in physical damage to the lens capsule. When the lens capsule is damaged, the inside of the lens expands to mix with water and becomes white due to the solidification of lens proteins. Allergic skin conditions can also cause the appearance of cataracts; one example is atopic dermatitis (AD) can cause cataracts, especially in children. The habit of rubbing the eyes in an allergic state can cause cataracts because, in AD conditions, the protein levels in the aqueous humour are high. Other skin diseases that can cause cataracts are poikiloderma, vascular tropics, scleroderma and keratosis follicular (11).

Aldose reductase enzyme is the enzyme that plays the most role in the formation of cataracts due to abnormalities in sugar metabolism. Poor nutritional conditions in cataract patients can cause proteins to become less soluble in the lens of the eye. Long-term use of medication can also cause the onset of cataracts. A steroid drug, prednisone, can block the metabolism of the tissues that support the lens. Steroid medication creams applied to the eyelids have the opportunity to increase intraocular pressure and cataracts. One of the mechanisms of steroids in causing cataracts is osmosis imbalance, oxidative damage or disruption of the lens development process. Oxidative damage to the lens can also be affected by alcohol consumption so that it can improve the condition of nuclear, cortical and posterior sub-capsular cataracts (9).

Cataracts can occur due to reduced glutathione and the presence of cation imbalance in the lens. An increase in lens pigmentation accompanies the most significant reduction in glutathione levels in the nucleus and cortex. This condition is also described as the disconnection of 12 nucleotides from the crystalline- β 2 gene, which is one of the most abundant types of crystalline polypeptides. This condition causes the loss of four amino acids that prevent the formation of proteins. These unformed proteins can cause cataracts. Cataracts of the scenes are also found to be altered in the protein arrangement of the lens, especially in the crystal- α and crystalline- γ . Changes in the makeup of these proteins can also cause proteolysis. This type of cataract also allows the breakdown of the main lens polypeptide in the terminal carboxyl group of the colistin- α and crystalline- γ into two parts (17).

The mechanism of the formation of selenium cataracts is explained as follows. Selenium oxidizes the sulfhydryl group of the calcium enzyme ATPase so that calcium can enter from the aqueous humour. An increase in calcium activates calpain (calcium-activated protease) and causes autolysis so that the sulfhydryl group is on the active side of alpine. The more active the sides of calpain, the more proteolysis occurs. Elongation of the N-

terminal group of the crystalline- β dimer form _dipecah by Kalpain. This change causes the exposure of charged groups so that the formation of aggregates and hydrophobic interactions can occur.

This mechanism can accumulate so that lens opacity and light scattering arise. Types of cataracts, according to (Eka. S 2012), are as follows: 1) Age-related cataracts (senile cataracts). Cyclic cataracts are the most common type of cataract, and ageing, dehydration, systemic disorders, and oxidative stress can cause them. The only symptoms are distortion of vision and increasingly blurred vision. Generally, patients who experience this type of cataract are over 50 years old; 2) Congenital children's cataracts. This type of cataract is most common from birth. Many congenital cataracts have no known cause, although there may be genetic factors. Infectious or metabolic diseases cause others or are related to various syndromes; 3) Cataracts in children are acquired. Cataracts that arise later and are usually related to specific causes. Cataracts are mainly caused by trauma, both blunt and translucent. Other causes are uveitis, eye infections, diabetes and long-term drug use; 4) Traumatic cataracts. The most commonly caused by injury to a foreign body in the lens or blunt trauma to the eyeball. The lens turns white immediately after the entry of a foreign object because the hole in the lens capsule causes humour aqueous and sometimes the corpus vitreum to enter the lens structure; 5) Complementary cataracts due to intraocular cataracts in lens physiology. Cataracts usually begin in the posterior subcapsular area and eventually affect the entire lens structure. Intraocular diseases that are often associated with the formation of cataracts are chronic or recurrent uveitis, glaucoma, retinitis pigmentosa, and retinal discharge; 6) Toxic cataracts (rare). Many cases in the 1930s were caused by the consumption of dinitrophenol, a drug to suppress appetite. Corticosteroids, both systemic and topical, taken for a long time can also cause lens clouding; 7) Cataracts due to radiation and electrical. Cataracts are caused by infrared rays, X-rays, UV rays and or due to strong electric currents. Patients who can develop this type of cataract usually have frequent exposure to sunlight, radiation and high electrical voltage.

Overview of Cataract Management

Cataract management is generally carried out surgically; no therapy can cure cataracts other than surgery. Several studies explain ways to reduce the development of cataracts, one of which is the consumption of antioxidants. In the early stages of cataracts, the use of glasses and contact lenses can help in clarifying vision (18). Surgical management is carried out if the patient feels that the cataract he is experiencing greatly affects his vision, so the patient's activities are disturbed. Cataract surgery is performed for 30 minutes. The target

of the surgery is the return of eye function with safe surgery and minimal surgical procedures, performed under topical anaesthesia, the most minor incision of the wound and the design of the lens that is easy to reclose. Suppose both eyes of the patient need surgery. In that case, the procedure is carried out alternately for one week to ensure that the procedure used in the first surgery does not cause significant complications so that it can be used in the second surgery (19).

Cataract surgery can be performed with several procedures. The first procedure is Intracapsular Cataract Extraction (ICCE) by replacing the entire lens (nucleus, cortex and capsule) indicated in patients who do require replacement of all lenses. Patients with lens dislocation conditions may get an ICCE surgical procedure. This procedure is rarely used compared to Extracapsular Cataract Extraction (ECCE). ECCE can be performed with smaller incisions compared to ICCE. The ECCE procedure extracts the nucleus and cortex. Then, it leaves the posterior part of the lens so that the onset of postoperative complications such as Cystoid Macular Edema (CME) can be reduced. After the upper edge of the cornea is incised, a transparent gel liquid is injected into the space between the cornea and the lens to prevent damage to the intraocular lens (IOL) (18).

The most widely used procedure today is phacoemulsification (PHACO). This technique uses an ultrasonic device to melt parts of the nucleus and cortex and then suck them up through a unique channel. The incision made is also smaller than ECCE so that the resulting wound can heal quickly. It is necessary to develop ultrasonic technology to support cataract surgery that is safe and does not provide meaningful complications. It is necessary to replace the lens structure that has been surgically performed either with aphakic eye-glasses, contact lenses or IOL implants. IOL implants are more commonly used during the cataract process and are inserted into the IOL pouch in front of the iris. IOL implants are contraindicated for patients who have had uveitis, diabetic retinopathy, neovascular glaucoma or irradiated rubeosis (19).

Overview of Corticosteroid Drug Side Effects

Drug side effects are any undesirable and inadvertent harmful effects of a drug that arise from the administration of a drug at standard doses to humans for prevention, diagnosis or therapy, as well as modification of physiological functions (5). There is much evidence that drug side effects (ESOs) can actually be prevented by increasing knowledge obtained from monitoring aspects of post-marketing drug safety or what is now better known as pharmacovigilance

In general, the long-term use of corticosteroid drugs is Cushing's syndrome, which is often caused by a tumour in the house and hyperproduction of ACTH. The main symptoms are fluid retention in the tissues that cause rapid weight gain, round face, atrophy and muscle weakness (myopathy devoid) specifically for the limbs and shoulders, osteoporosis (brittle bones), growth retardation in children due to accelerated closure of the epiphysis of the pipe, skin atrophy With striae, which are bluish lines due to bleeding under the skin, as well as wounds that are difficult to heal due to inhibition of the formation of granulating tissues, Diabetogen Decreased glucose tolerance can cause hyperglycemia with the effect of manifesting or intensifying diabetes. The cause is the stimulation of excessive glucose formation in the liver, Immunosuppression, which suppresses the body's reaction to fend off, as occurs in organ transplants. The number and activity of T/B lymphocytes are reduced at very high doses, as well as the production of antibodies. The effect is a decrease in repellents and the body becomes more sensitive to infection by small services (6).

Excessive use and extended periods topically will impact the onset of cataracts and glaucoma, which are characterized by increased eyeball pressure and visual impairment (2). This study aims to provide an overview of the side effects and duration of use of corticosteroid eye drops.

RESEARCH METHOD

This study was carried out by a cross-sectional method that was analyzed descriptively with a universal sampling method with inclusion criteria. These, namely, patients who came to control within one month after surgery, while patients who did not come to control within one month, were included in the exclusion criteria. Data collection was carried out at the KMU Madura Eye Clinic Pharmacy Installation in May-June 2024 by conducting interviews about the side effects of using corticosteroid drugs and also by looking at medical records. The inclusion criteria in this study are as follows: 1) Patients who have undergone cataract surgery; 2) Patients aged 50-80 years; 3) Getting corticosteroid therapy; 4) Perform post-operative control at KMU Madura Eye Clinic.

The exclusion criteria in this study include patients who do not perform surgical control at the KMU Madura Eye Clinic. The sampling method uses non-random sampling with the time limited sampling method, which is to take all data from the patient's Medical Record (RMK) that meets the inclusion criteria. The data collection method is to find and collect Health Medical Records of patients who have undergone cataract surgery and received corticosteroid therapy after cataract surgery at the KMU Madura Eye Clinic in the period May – July 2024 and meet the inclusion criteria of 100 people. Then, based on the Health

Medical Records, it is recorded on the data collection sheet as follows: 1) Patient's identity (medical record number, name, age, and gender); 2) Date of cataract surgery; 3) History of diseases and medical history; 4) Doctor's diagnosis, clinical symptoms and patient complaints; 5) Clinic data; 6) Cataract surgery accepted (PHACO or ECCE); 7) Corticosteroid therapy includes the type of corticosteroid along with the dosage form, dose, route of administration, frequency of administration, and duration of therapy; 8) Therapy response (including side effects through interviews)

The data obtained from the data collection sheet were entered into the master table including the patient's identity (medical record number, name, age, and gender), date of cataract surgery, diagnosis, clinical symptoms, complaints, disease history, treatment history, clinical data (body temperature, RR, pulse, blood pressure), therapy data (type of corticosteroid along with dosage form, dose, route of administration, frequency of administration, and duration of therapy) after undergoing cataract surgery at KMU Madura Eye Clinic. Then it is processed statistically and presented data in the form of diagrams, tables, graphs or narratives.

RESULT AND DISCUSSION

In this study, several data related to patient characteristics were obtained which are presented in the table below

Table 1. Description of the characteristics of the research subjects

Characteristics of Respondents	N= 60	
	Number of Respondents	Percentage (%)
Gender		
a. Man	35	58
b. Woman	25	42
Age		
a. <20	4	6,70
b. 20-39	12	20
c. 40-59	24	40
d. >60	16	26,70
Length of Use of Corticosteroid Eye Drops		
a. <7	2	3,30
b. 7 to 30	12	20
c. >30	46	76,70
Use of TIO Lowering Eye Drops		

a. Yes	24	40
b. Not	46	76,70

Most respondents were male patients (58.42%) aged 40-59 years (40.05%), using corticosteroid drugs for >30 days (78.46%), and also experienced an increase in TIO 46 respondents (76.70%). Duration of use of corticosteroid eye drops in the group of post-cataract surgery patients at KMU Madura Eye Clinic. A total of 46 patients used corticosteroid eye drops after cataract surgery for more than 30 days. 12 patients used it for a range of 7-30 days, and only 2 postoperative patients used corticosteroid eye drops for less than 7 days. This is in accordance with what Hutauruk wrote that the use of corticosteroid drops after cataract surgery is for 4-6 weeks.

Use of Corticosteroid Eye Drops in Patients after Cataract Surgery

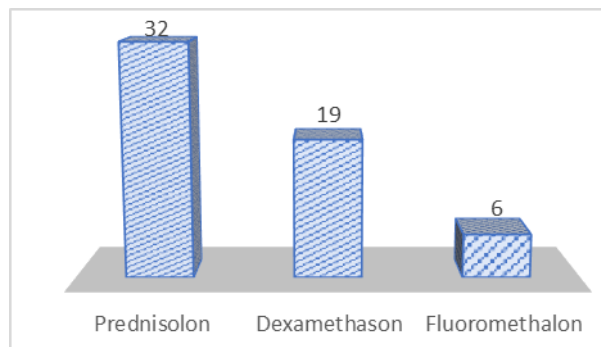


Figure 1. Frequency of Use of Corticosteroid Drugs in Post-Cataract Surgery Patients

From the results obtained, it is explained that the most widely used drops for postoperative cataract patients are prednisolone by 53.3%, dexamethasone by 31.67% and 10% who take fluorometholon drugs.

Number of Drug Side Effects Incidence in Postoperative Patients Using Corticosteroid Drops

The most common side effects were found in patients who used prednisolone (40.0%). The most potential and most common side effects of prednisolone use are opacity, itching and stinging. Then followed by the side effects of dexamethasone use by 30.0%. As for the side effects of fluorometholone eye drops are sore, opaque and red (4). In this study, as many as 11 patients experienced an opaque effect; none complained of hot eyes, and 16 patients complained of soreness (5)(6). According to Husna 2019, the side effects experienced by patients will vary. Common side effects are red eyes, slight glare when seeing light, and blurred vision. However, these side effects are only temporary.

In this study, as many as 15.1% of patients did not experience. Side effects: 26.67% of patients experienced soreness, and 18.30% of patients complained of opacity. Patients who experienced side effects of redness, dizziness, and itching were 13.08% each. Moreover, as many as 23.34% of patients experienced combined side effects. Topical corticosteroids have dangerous side effects in the long term, namely glaucoma, which can start at any time after use, 2 weeks or more or in the following year. The mechanism by which corticosteroids cause an increase in TIO is the accumulation of glycosaminoglycans (GAG) or increased protein production in the woven trabecular meshwork, resulting in obstruction of the outflow of the aqueous humour. Corticosteroids also cause a decrease in the synthesis of prostaglandins that regulate the aqueous humour facility or excretion, increasing intraocular pressure (7).

Table 2 Number of Occurrences of Drug Side Effects in Postoperative Cataract Patients Using Corticosteroid Eye Drops

Medicine	Number of ESO Incidents	Percentage (%)
Dexamethasone		
Sore	9	47,30
red	6	31,57
Itching	3	15,78
No Ice	1	5,26
Prednisolone		
Dizzy	2	6,25
Blurry	9	28,12
Pain	4	12,50
Red	2	6,25
Itching, Pain	4	12,50
Red, Ganjal	3	9,37
No Ice	8	25,00
Fluorometholone		
Blurry	2	33,33
Pain	3	50
Red	1	16,67
No Ice	0	0

Some of the Relationships Between Types of Corticosteroid Eye Drops and Side Effects Experienced by Patients

Table 3 Relationship between Drug Type and Total Length of Use with Side Effects

Relationship	p-value	Test
Type of Drug vs Side Effects	0,06	Kruskall-Wallis Test
Total length of treatment vs Side effects	0,03	Chi-Square

Based on Table 3, it was shown that the relationship between the type of advanced corticosteroid eye drops and the side effects experienced by the patients showed that there was no significant difference between the type of advanced corticosteroid eye drops and the side effects experienced by the patients. The length of use of the drug indicates a meaningful relationship. The pediatric population usually has side effects that are difficult to encounter because their ability to communicate symptoms is still limited. As for geriatric patients, drug side effects are more common due to a decrease in physiological and metabolic function (8).

CONCLUSION

The length of use of corticosteroid eye drops in patients after cataract surgery at the KMU Madura eye clinic pharmacy installation is more than 30 days. The side effects experienced by patients in use corticosteroid eye drops include: 1) Dexamethasone: stinging (47%), red (31%), itching (15%), no ES (5%); 2) Prednisolone: dizziness (6%), blurred (28%), (stinging 12%), red (6%), itching, stinging (12%), red, odd (9%), no ice (25%); 3) Fluorometholone: Blurred (33%), Stinging (50%), Red (16%), no ESO (0%).

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