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REVIEW ARTICLE **OPEN ACCESS**

Eslicarbazepine: A Prospective Review

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ABSTRACT
Clinical studies have shown that ESL helps people with focal seizures that won't go away or who have just been diagnosed with them, whether they use it alone or with other treatments. This medication provides numerous benefits compared to CMZ and OXC, two other medications in the DBZ-CBX family. Therefore, in our review, we have chosen to assess and discuss ESL.
Key words: *DBZ, CBX,ESL, seizure, treatment.*

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INTRODUCTION

Studies have been proving that "eslicarbazepine acetate (ESL) is a novel AED that has been approved by the European Medicines Agency and the US Food and Drug Administration as monotherapy and recently adjunctive therapy for focal onset seizures (FOS), with or without secondary generalization, in adults".[1] Studies have also provedtaht , "ESL was also recently approved for use in children and adolescents as an adjunctive therapy".[2]Studies have been proving that the "dibenzazepine (DBZ) family of AEDs, which also comprises carbamazepine (CBZ) and oxcarbazepine (OXC) [Benes et al. 1999], contains ESL, a third-generation member".[3]

PHARMACOLOGY

Moreover, studies have shown that the "structural difference at the 10,11 location of the dibenzazepine nucleus imparts ESL's distinct pharmacodynamics and pharmacokinetics".[4] Studies have demonstrated that "ESL has a comparable affinity to the inactivated state of CBZ and a three fold lower affinity to the resting state of VGSC".[5] Various sytudies have also proved that , "unlike traditional sodium channel blockers that interfere with the rapid inactivation process, ESL reduces the availability of VGSC by selectively increasing slow inactivation, similar to lacosamide".[5,6] Furthermore, studies have concluded that ,"these properties result in the stabilization of hyperexcitable membrane, inhibition of long-term repetitive generation of action potentials common to neurons involved in epilepsy, and reduction of long term channel availability, with low potential to disrupt physiological function".[7] Studies have also shown that ESL is a great oral prodrug, with a high bioavailability of around 94%. It's quickly and completely converted to its main active metabolite, eslacarbazepine, in the liver through first-pass hydrolysis, which is why the amount of ESL in plasma is usually lower than what's measured.[8]

DOSAGE [6]

Research has demonstrated that Early estrangement ,"ESL is an oral alternative electrolyte (AED) administered orally, either in liquid suspension form or in tablet form, and can be ingested with or without sustenance".[6] Studies also proved that ,"the recommended initial dose of ESLT is 400 mg per day, with an increase to 800 mg per day after 1-2 weeks; depending on individual response, an additional dose may be administered as an adjunctive treatment to ESLT, with an additional dose of 1,200mg per day".[6] Studies have proved that ,"plasma levels demonstrate a linear relationship with ESLT posology, however, no therapeutic range has been established".[6]

CONTRAINDICATION [9]

1. People with 2nd or 3rd degree atrioventricular block

2. Any type of heart block
3. Patients hypersenistive to ES, oxcarbazepine (OZ) or carbamazepine(CZ)

CONVENTIONAL TREATMENT ASPECT

1. Renal & Hepatic Impairment [9]

Studies have shown that, "ESL metabolites are removed from the systemic circulation primarily by renal excretion, and clearance is dependent on renal function in patients with mild to severe renal impairment". Furthermore, studies have shown that, "no dose adjustment was required if creatinine clearance (CrCl) was > 60 mL/min". Various studies concluded that, for "patients with CrCl between 30 and 60 mL/min, the initial ESL dose was 200 mg once daily or 400 mg every other day for 2 weeks, then increase by 400 mg once daily to 600 mg". Researchers through their studies concluded that, the "amount can be increased up to per min". Additionally, studies have shown that, "ESL was not recommended for patients with severe renal impairment (CrCl < 30 mL/min) due to insufficient data". According to studies, "hemodialysis partially removes ESL and its metabolites from plasma". Studies also shown that, "liver function(LF) has a less significant effect on pharmacokinetics in patients with ESL and mild to moderate liver impairment". So, studies have proved that ,"no dosage adjustments were required". Conversely, studies have also concluded that, "this drug has not been studied in cases of severe LD and was not recommended for use in this case also".

2. Drug Interaction [1]

Studies have shown that "increased doses of drugs primarily metabolized by CYP3A4 (e.g. simvastatin) or eliminated by conjugation via UDP-glucuronyl transferase may be necessary when administered concomitantly with ESL because of side effects. its sensor. although weaker than CBZ".[1] Researchers have demonstrated that "ESL has CYP2C19 inhibitory properties and interactions may occur when ESL is administered with drugs that are substrates of this enzyme (e.g., diazepam)".[1]

3. Oral Anticoagulant & Digoxin

According to various studies, it was concluded that, due to the "interindividual variability in the interaction, it is, however, advisable to carefully monitor the international normalized ratio during the first weeks after initiating or ending concomitant treatment of warfarin and ESL".[9] Studies have also concluded that , "ESL at the daily dose of 1,200 mg decreases plasma exposure to S-warfarin by 23% without significant effects on R-warfarin pharmacokinetics or coagulation".[9] Reserachers also concluded that , "no studies have explicitly investigated the possibility of pharmacological interactions between ESL and direct oral anticoagulants; however, this does not mean that such interactions do not occur".[9] Studies have alos shown that , it has been determined that ESL does not have an effect on the pharmacokinetics of digoxin, suggesting that there are no significant interactions with the transporter P-glycoprotein.[9]

4. Antiepileptic Drug [1]

Studies have shown that combining ESL and CBZ reduces exposure to ES by an average of 32%. Furthermore, studies have shown that this decrease is most likely due to an increase in glucuronidation, which may necessitate an adjustment in the ESL dosage. According to many studies, it is interesting that when ESL and CBZ are used together, there is a higher likelihood of experiencing diplopia, abnormal coordination, and dizziness. Studies have also shown that ,when both ESL and phenytoin are taken at the same time, the amount of the active metabolite ES in the body drops by about one-third. ESL-caused increases in glucuronidation are to blame for this reduction. Additionally, studies have shown that, the inhibition of CYP2C19 by ESL results in an increase of 31-35% in the body's phenytoin levels. Based on the individual's response, it may be necessary to increase the dose of ESL and decrease the dose of phenytoin.

5. Fertility , Pregnancy & Lactation

Studies have shown that the vast majority of people with epilepsy can and do go through normal daily activities, including having children. Various other studies have shown that three to five out of every thousand pregnancies will result in a baby born to a woman with epilepsy, making the frequency of epilepsy among pregnant women as high as 0.7%.[10,11] Researchers also concluded that, while the dangers associated with epilepsy and some of the older antiepileptic pharmaceutical drugs have been largely elucidated via global registries and observational studies, a significant information vacuum exists for the majority of the newer ones, ESL included.[12]

ADVERSE EFFECT

Research has indicated that the adverse impacts of this substance bear a striking resemblance to those of oxcarbazepine.[13] Furthermore, research has indicated that fatigue and lightheadedness are prevalent among patients, with a prevalence rate exceeding 10%.[13] Studies have shown that "there are some

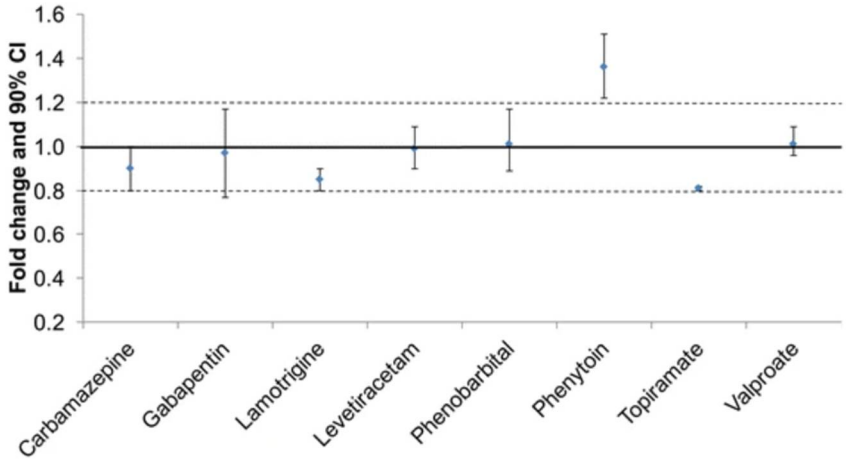
commonly experienced side effects, such as poor coordination, gastrointestinal issues like diarrhea, nausea, and vomiting, rash (1.1%), and hyponatremia (low sodium blood levels, 1.2%)".[13] Studies have shown that these side effects may be experienced in approximately 1–10% of cases.[13] Several research studies have indicated a potential heightened risk of experiencing suicidal thoughts. Here is a reference to a source.[13]

OVERDOSE

Studies have concluded that, standard doses have side effects that are similar to those of an overdose.[13] Various studies have shown that ,"these include severe hyponatremia, sleepiness, hemiparesis (weakness on one side of the body), hemiplegia, and problems with the eyes and stomach."[13] Studies have concluded that , there is currently no specific antidote available. It is possible to dialyze eslicarbazepine and its metabolites.[13]

INTERACTION

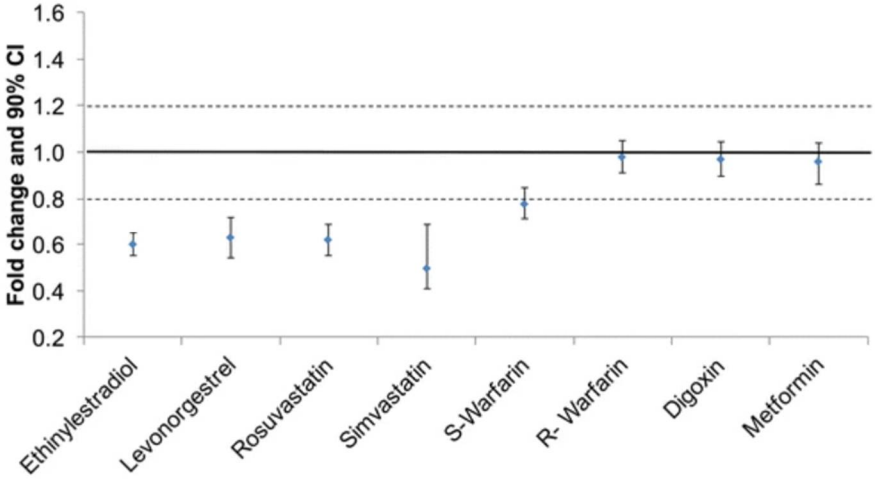
It was discovered that ESL, like oxcarbazepine, has a small effect on the activity of CYP3A4 and uridine 5'-diphospho-glucuronosyl, but not as much as carbamazepine.[14] They also found that the effect isn't strong enough when combined with ESL to change how many AEDs these enzymes break down (Graph 1).[15] Additionally, studies concluded that women who are in the age range where they can have children might require a higher dosage of oral contraceptives to counteract this effect, or they can consider using different methods of contraception (Graph 1)



Graph 1 : **Effect of ESL on other ant-epileptic drug**.

According to study , "when ESL is used with phenytoin, the dose of phenytoin may need to be adjusted downward. However, the doses of gabapentin, lamotrigine, levitiracetam, phenobarbital, topiramate, carbamazepine, or valproate may be kept the same when eslicarbazepine acetate is also administered at the same time".(Graph 1) [16]

Furthermore, studies concluded that ESL has an edge over carbamazepine as it helps to decrease the occurrence of drug interactions. ESL, on the other hand, may make hormonal birth control less effective because it affects CYP3A4, a protein that breaks down levonorgestrel and ethinylestradiol (Fig. 6).[17]



Graph 2 : Effects of ESL on other drugs.

Studies have found that "ESL makes it easier for oral contraceptives to work, which means that the dose of the contraceptive needs to be changed or a non-hormonal method of birth control needs to be switched to. It also makes simvastatin and rosuvastatin leave the body more quickly, which means that if lipid levels change a lot, the doses of these drugs may need to be changed as well. When used with digoxin or metformin, eslicarbazepine acetate does not need a dosage modification".(Graph 2) [16]
Studies have found that it is recommended to evaluate the response to therapy (for example, cholesterol levels) and to increase the dosage of these medications if necessary (Graph 2). [18, 19] Studies also showed that ESL lowers the average amount of simvastatin and rosuvastatin that the body is exposed to by 54% and 36–39%, respectively. This is because ESL decreases the level of mean systemic exposure to rosuvastatin. Thus, studies confirmed that ESL decreases the levels of mean systemic exposure to rosuvastatin by 54%. Additionally, it has been demonstrated that ESL lowers the amounts of (S)-warfarin by 23%. However, it does not change the way (R)-warfarin works or how it clots blood.[20] It may be crucial to keep a careful eye on the international normalized ratio for patients who have recently started taking ESL and are also receiving warfarin. It would seem that using ESL does not have any effect on the pharmacokinetics of digoxin or metformin that is significant from a clinical standpoint. [21,22]

SAFETY

Studies have found that ESL is widely regarded as a safe and well-tolerated medication. Furthermore, studies have been proving that the most common side effects are vertigo, cephalalgia, weariness, and double vision. [23,24,25,26] The results of some studies also showed that sleepiness, poor coordination, vomiting, and vision problems may happen, but most of the time they are mild to moderate. [27]. A study conducted on a sample of 247 patients who were using eslicarbazepine as an additional treatment revealed that 3.7% of the patients encountered a severe negative occurrence, such as hyponatremia and allergic skin responses.[28] Studies have found that lengthy research periods have demonstrated the reliability of the findings. About 51% of the 314 people who took part in the open-label extension trial for eslicarbazepine said that the medicine made them feel bad, and 97% of those effects were considered to be mild to moderate.[29] The study was conducted to determine whether or not eslicarbazepine might be used to treat patients with schizophrenia. The incidence of adverse events was greatest during the first three months of therapy, when it reached 35%, compared to an incidence of 12.7% during the final three months of the trial.[29] Studies have also concluded that, due to these adverse effects, only 3.5% of patients stopped taking their therapy. The studies also found that patients spontaneously reported 367 serious adverse events and 509 non-serious adverse events over a period of 434,468.3 patient-months in 18 different countries across Europe from October 1, 2009, to October 21, 2013.[30] This information was gleaned from the study that took place between October 1, 2009, and October 21, 2013. Furthermore, studies have concluded that the most common of these symptoms was hyponatremia, which was reported 114 times; the next most common symptom was convulsions, which were reported 48 times; and finally, dizziness was reported 29 times.[31]
Studies have found that certain antiepileptic drugs, such as oxcarbazepine and carbamazepine, are known to have a significant adverse effect that is referred to as hyponatremia.[32,33] Various studies have also concluded that while using eslicarbazepine, only 0.6%–1.5% of patients develop hyponatremia, which is a much lower incidence than the one reported with these other medications. [34,35,36] In a randomized, double-blind, placebo-controlled phase III trial of 653, it was found that 1.5% of patients taking eslicarbazepine suffered from hyponatremia, but 0% of patients taking placebo did.[26] In the same study, the bulk of the sodium reduction took place during the first eight weeks of therapy, after which the level stabilized. In 1.4% of patients taking 1200 mg of ESL, hyponatremia was severe enough to justify cessation; however, hyponatremia was not a rationale for discontinuation in any of the patients taking 800 mg.[26] To be more specific,studies have concluded that older patients who have ESL and are suffering convulsions after a stroke are more likely to develop hyponatremia. It was found in a 2-year observational study of 32 such patients that 12.5% had hyponatremia while taking 400 mg to 1200 mg of ESL daily. This finding indicates that monitoring the blood sodium level is required in this group.[37] Studies have found that ESL has exhibited a safety profile that is either superior to that of oxcarbazepine or at least equivalent to that of carbamazepine. "Ley et al. carried out a study on a total of 108 patients who received ESL".[32] Additionally, studies have concluded that it was discovered that 52% of these patients had been taking either carbamazepine or oxcarbazepine in the past.[38] Also, other research has found that when people started ESL therapy, their average levels of low-density lipoprotein, total cholesterol, and triglycerides went down in a way that was statistically significant. [38] Furthermore, studies have concluded that quite often, the readings shift from being pathological to being benign. In this regard, studies have also concluded that before and after starting eslicarbazepine, there was no discernible change in the liver function tests. ESL, in contrast to carbamazepine, does not have the effect

of reducing the number of leukocytes in the body. Here, studies have also concluded that, as a relatively new medication, ESL has shown some encouraging outcomes in terms of the safety of its use.[31]

CONCLUSION

We come to conclude that, the antiepileptic drug ESL has been shown to be both effective and safe in the treatment of people who suffer from seizures with partial onset. This medication offers a lot of advantages over CMZ and OXC, two additional medications that belong to the DBZ-carboxamide (CBX) family. Because of its pharmacological nature, it is only necessary to administer the medication once a day. This may help boost patient compliance. ESL is a weaker enzyme inducer than CMZ, hence reducing the likelihood of adverse drug interactions. When compared to CMZ and OXC, the likelihood of developing hyponatremia when using ESL is much reduced. Its efficacy is equivalent to that of CMZ, and the side effects that it causes are typically mild to moderate in intensity.

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