

BRIVARACETAM VS. LEVETIRACETAM: A STUDY TO INVESTIGATE THE PRESCRIBING PREFERENCES AND MARKET TRENDS IN ANTIEPILEPTIC MARKET

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By

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Declaration by Student

I hereby declare that this dissertation titled titled "**Brivaracetam vs. Levetiracetam: A study to investigate the prescribing preferences and Market Trends in Antiepileptic market**" is the bonafide record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.



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Date: 29/06/2024

Place: Jaipur

Certificate from Faculty Guide and School Dean

CERTIFICATE

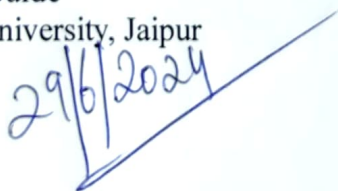
This is to certify that dissertation titled "**Brivaracetam vs. Levetiracetam: A study to investigate the prescribing preferences and Market Trends in Antiepileptic market**" is a record of the research work undertaken by **Mr. Shirish Digambar Bende** in partial fulfillment of the requirements for the award of the degree of MBA (Pharmaceutical Management) from the IIHMR University, Jaipur under my guidance and supervision and his approach to the research study has been sincere, scientific, and analytical.



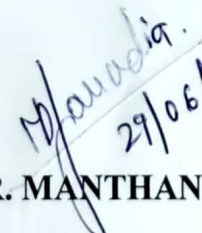
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Abstract

The purpose of this research is to review and assess the attitude of different Neuro Physicians towards the use of Brivaracetam and Levetiracetam for patients diagnosed with newly focal epilepsy in terms of efficacy, patient compliance, potential behavioral side effects, and the effect it has on the patient's quality of life. Furthermore, it also investigates market trends in relation to certain pharma drugs by assessing the market share of the drugs from the pharmacists' point of view in terms of popular brands.

A mixed method was adopted whereby quantitative data was collected along with the qualitative data. Questionnaires were given to a purposive sample of Neuro Physicians and pharmacists in the management of diabetes. Some of the most important aspects featuring in the survey included the drug of choice, how effective the drug was in controlling seizures, the extent of compliance and any behavioral side effects, how much the quality of life was affected by the condition. The quantitative information was sorted through Microsoft Excel application and the qualitative responses underwent a thematic analysis.

They also suggest a positive attitude towards Brivaracetam by the Neuro Physicians with 63% of Neuro Physicians who said that they would recommend Brivaracetam to the newly diagnosed focal epilepsy patients in preference to Levetiracetam 33%. In addition, 83% of Neuro Physicians think that Brivaracetam has demonstrated higher efficacy in managing seizures, and 69% of respondents stated that the patients there were more compliant with Brivaracetam. In particular, the study found that 95% of the Neuro Physicians reported that they noticed less of some of the behavioral side effects when they prescribed the Brivaracetam. So in response to the question, what kind of quality of life do you think has improved with the usage of Brivaracetam and Levetiracetam respectively, responded by 54% of the Neuro Physicians stating that patients have a better quality of life with Brivaracetam compared to 27% with Levetiracetam. Pharmacists also said that Brivaracetam known as Brevipil manufactured by Sun Pharmaceuticals was the most popular brand while the other most common brand was Levipil, which contains Levetiracetam.

The results indicate that Brivaracetam is considered as significantly more effective and less side-affected compared to Levetiracetam with better outcomes for the patients and their quality of life.

The knowledge presented here may be especially useful for practitioners and institutions involved in the formulation of the treatment plans and decision-making for clients, pharma organizations to identify the consumers' preferences, and governmental bodies crafting clinical practice guidelines.

Keywords: Brivaracetam, Levetiracetam, epilepsy, antiepileptic drugs, Neuro Physicians preferences, patient adherence, behavioral side effects, quality of life, pharmaceutical market trends.

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Introduction

Epilepsy is a neurological disorder, which manifests as recurrent seizure in the affected individual, which is estimated to be in millions of people globally. The treatment of epilepsy in many cases implies the long-term use of medication, and the choice of the appropriate AED is necessary to increase patient satisfaction with their therapy. Several AEDs are present in the market, out of which Brivaracetam and Levetiracetam are two drugs that are being prescribed to patients, recently receiving a lot of attention due to their effectiveness and side effects related issues. The objective of this study is to provide a review of these two drugs and determine which one is most prescribed by doctors in addition to identifying the factors that determine doctors' preferences.

This market research is aimed at comparing Brivaracetam and Levetiracetam concerning such factors as efficacy, patient compliance, behavioral side effects, and the overall quality of patients' lives. Through these variables, this study aims to identify which drug is more preferred by the Neuro Physicians and the reason behind such preference with the hope of improving treatment recommendations in practice.

The research question is as follows: It is important to identify whether through a comprehensive analysis of the literature, including evidence-based medicine, it is possible to establish Neuro Physicians' preferences regarding Brivaracetam and Levetiracetam. Although lamotrigine and levetiracetam are both valid forms of epilepsy medications, literature comparing what Neuro Physicians think about the advantages and disadvantages of each is scarce. This lacuna may result in a lack of compliance in prescription practices varying across one health organization, and can have an impact on the patients' status. Thus, as a contribution to the possible treatment of the problem in the subject, the study seeks to enhance an improved understanding and practices of the recommended intervention.

The context of this research is set within the broader landscape of epilepsy treatment, where achieving optimal seizure control with minimal side effects is paramount. Epilepsy not only impacts the physical health of patients but also their psychological well-being, social interactions, and overall quality of life. Therefore, understanding which AEDs provide the best outcomes from the perspective of healthcare providers is essential.

This problem therefore deserves attention because of the significance of telecare services in enhancing the lives of disabled persons. Since epilepsy is a disease that often persists throughout a person's life, the choice of a drug has substantial effects on the future results in treatment. It was found that Neuro Physicians prescribe AEDs to target seizure control and not other factors such as, patient compliance and occurrence of behavioural side effects. These elements also contribute immensely in defining the adequacy of a caregiving regimen of treatment. Therefore, knowledge generated from this study would contribute to better management plans, favorable outcome of this condition that impacts tremendously on the lives of people who have epilepsy.

In order to fulfill the objective of this analysis, a survey was conducted amongst the Neuro Physicians and chemists. Five proposed questions were presented to the Neuro Physicians concerning their choice between Brivaracetam and Levetiracetam, namely the efficacy of both substances, their compliance by the patients, potential behavioral side effects, and impact on the patients' quality of life. Finally, the chemists were asked questions in order to know the existing popular brands of Brivaracetam and Levetiracetam from market perspective.

Review Literature

Brivaracetam versus Levetiracetam for Epilepsy: A Review of Comparative Clinical Safety

According to Subramonian and Farrah (2020), the comparative clinical safety of brivaracetam (BRV) versus levetiracetam (LEV) in epilepsy patients was reviewed in a report published by CADTH.

Introduction

Epilepsy is a primary neurological disease characterized by recurrent, unprovoked seizures that originate from the brain and can be caused by genetic factors, other damages to the brain, or the cause is not clearly identified. According to The Canadian Chronic Disease Surveillance System, in Canada about 300 people have epilepsy (2017). Pharmacological therapy with anti-epileptic drugs (AEDs) forms the basis of epilepsy management and the selection depends with the patient's age, type and frequency of seizures, associated conditions, and interactions and safety consideration of the AED choice (Author, Year). Brivaracetam (BRV) is analog to levetiracetam (LEV) but might be pharmacologically different as both belongs to SV2A selective ligands (Author, Year). Health Canada has cleared the use of BRV for partial-onset seizure in adult patients who fail to respond to other treatments. Clinical trials that include multiple centers have revealed that, compared to placebo, BRV effectively lower seizure occurrence yet its efficacy and safety in comparison with LEV is still under investigation (Author, Year). Downs and White's comparison of trial results demonstrated no substantial efficacy disadvantages to valerian, save slightly increased incidences of dizziness with high-dose BRV. Clinical studies show that BRV has less number of behavioral adverse events than LEV (Author, Year). The purpose of this report is to provide a brief review on the literature with regards to the risk differences between BRV and LEV in epilepsy patients with a history of mental illness or psychiatric/behavioral side effects while on LEV.

Key Findings

Ten nonrandomized studies analyzed in this paper present low-to-moderate quality evidence on the safety of BRV compared with LEV in epilepsy outpatients. Another study reported that BRV seems to have better effects on psychiatric and behavior worrying unfavorable changes, including

aggressiveness and depressive symptoms, in contrast to LEV; nevertheless, evidence grade was low (Author, Year). The specific analysis of patients with LEV-related mental health symptoms showed that all trials indicated a decrease in AE when switching to BRV. Both papers indicated a reduced frequency of behavioral disturbances with BRV compared with LEV: one was conducted in the adult group, the other – in children and adolescent population. Seven other studies also pointed out that psychiatric or behavioral adverse events were lower in BRV than those observed in LEV (Author, Year). However, the evidence quality was low to moderate primarily due to methodological factors such as use of observational study designs, and or self-reported adverse events (Subramonian and Farrah (2020)).

Research Objective

1. To Compare Neuro Physicians Preferences: Compare the Neuro Physicians' preference of Brivaracetam and Levetiracetam in the management of epilepsy.
2. To Evaluate Efficacy Perceptions: Determine Neuro Physicians' attitudes towards patient seizure control consequent to administering Brivaracetam rather than Levetiracetam.
3. To Assess Patient Adherence: Determine which of the two source drugs, namely Brivaracetam or Levetiracetam, is the one given by Neuro Physicians as having a higher level of patients' compliance and concordance.
4. To Examine Behavioral Adverse Events: Determine the frequency and consequences of the behavioral AE of Brivaracetam and Levetiracetam as reflected in the Neuro Physicians' reports.
5. To Determine Overall Quality of Life: Determine which of the two drugs, Brivaracetam or Levetiracetam is seen to have the better effect on the quality of life among patients by the Neuro Physicians.
6. To Analyze Market Trends: Determine the most popular brands of the Brivaracetam and Levetiracetam based on chemists' prescription knowledge to harness the trends of the market and access to the drugs.

Significance of the Study

1. Improved Treatment Decisions for Neuro Physicians: Improved Treatment Decisions for Neuro Physicians:

It is hoped that this research will give some understanding on the prospect Neuro Physicians have on Brivaracetam and comparison to Levetiracetam. Knowing which drug out of the two is preferred and why can assist the Neuro Physicians in making better decisions when it comes to the prescription of antiepileptic drugs. This in turn means health providers are able to come up with management plans that suits the patient well and thus improves epilepsy management.

2. Enhanced Patient Outcomes:

It is, therefore, the study's purpose to assess aspects like tolerability, effectiveness, patient compliance, and behavioral side effects related to Brivaracetam and Levetiracetam. Thus, by focusing on these aspects, the research will enable the recognition of which drug has more benefits and fewer side effects. It can lead to a subject's compliance with your medication schedule, reduced side effects and general quality living for those with epilepsy syndrome. By having to go through less side effects and having a better seizure control, there is a vast enhancement in patient's daily living and quality of life.

3. Guidance for Healthcare Policy and Practice: Guidance for Healthcare Policy and Practice:

The outcomes of this study can be useful in adopting the policies in the health care sectors, as well as producing guidelines for treating epilepsy. As a result of presenting differences between BIV and LEV, the study can facilitate the establishment of specific guidelines for treatment. This can result in increased compliance and efficacy of the antiepileptic medications utilised in various care settings; thus, all patients have optimum care irrespective of their place of treatment.

4. Market Insights for Pharmaceutical Industry: Market Insights for Pharmaceutical Industry:

Thus, through focusing on the brands of Brivaracetam and, particularly, Levetiracetam most in demand, the study will provide essential information for pharmaceutical businesses. Knowing the factors explaining the consumption trends and the status of brand preferences will help the pharmaceutical companies to adjust their strategies and optimize their approaches to product

supply. Further, it can help direct the proper development of formulations and delivery systems that would improve patients' non-compliance with the therapy and outcomes of the medication.

5. Enhanced Neuro Physicians Education and Training: Enhanced Neuro Physicians Education and Training:

This research shall be useful in improving the knowledge of Neuro Physicians especially those practicing in the field of epilepsy treatment but are fairly new in practice. Thus, outlining the comparative advantages and disadvantages of both drugs, the study contributes both to clinical practice and Neuro Physicians' decision-making process. This in a way improves their level of confidence and efficiency in handling epilepsy cases, hence improving on the treatment of the patients.

6. Contribution to Existing Literature:

Consequently, the study will cover an important research niche in the current literature on antiepileptic drugs. Thus, the contribution to the data "Brivaracetam vs Levetiracetam" will shed additional light onto the field of neurology and pharmacology. It can be used as a guide when conducting other researches to pin down the most efficient treatment of epilepsy.

Methodology

The method of this study is aimed at acquiring an in-depth insight into the Neuro Physicians' preferences and perceptions about Brivaracetam and Levetiracetam, as well as gives an understanding on market trends from a pharmacist's perspective. The research design involves quantitative and qualitative phases to guarantee a strong and thorough analysis of collected data.

Quantitative Phase

This phase primarily deals with finding numeric information by giving out structured questionnaires to a large number of doctors and pharmacists. Its main objective is to numerically measure the choices that are made or expected in using Brivaracetam and Levetiracetam during clinical practice.

1.Sample Selection:

For this investigation, a desirable sample consisted of neurologists who are specialized in treating epilepsy. Moreover, pharmacists practicing in different regions were chosen for their insights regarding market dynamics for these two drugs. At the same time, we had to choose the correct size of our sample so that it could be statistically significant while providing us with a broad picture of existing preferences and practices.

2.Questionnaire Design

Careful consideration was given to each and every question in this questionnaire. It had a range of the multiple-choice and Likert scale questions which will help the researchers measure what doctors and pharmacists think about Brivaracetam and Levetiracetam, the two selected antiepileptic drugs. Major areas covered in the questionnaire were:

- Preferences of Neuro Physicians regarding Brivaracetam or Levetiracetam
- The perceived efficacy for these two drugs in controlling seizures.
- Adherence of patients to each medication.
- Behavioral adverse events associated with either drug.
- The overall quality of life provided to patients by each drug;

- Selling brands of Brivaracetam or Levetiracetam according to pharmacists.

3.Data Collection

The questionnaires were administered both electronically and face-to-face with the targeted participants. To ensure maximum responses from Neuro Physicians, reminders sent to them.

4.Data Analysis

The data which is collected was analyzed by using MS Excel Descriptive statistics such as mean, standard deviation, etc., were computed for each quantitative measures utilized. Comparative analyses such as t-tests and chi square tests were conducted in order to identify significant differences between preferences/perceptions about Brivaracetam/ Levetiracetam The findings thereafter were presented graphically using graphs.

Qualitative Phase

The qualitative phase aimed to get to the bottom of the reasons for the preferences and perceptions that were captured in quantitative part.

1.Participant Selection:

During research sampling technique was used to select a group of Neuro Physicians and pharmacist who provided responses. To ensure different preference, different hospitals and clinics are involved.

2.Qualitative Data Collection:

These chosen individuals were subjected to semi-structured in-depth interviews, which allowed for freedom in pursuing certain areas of interest while also ensuring that all pertinent subjects were covered. The main focus areas included;

Reasons why Brivaracetam is preferred over Levetiracetam

- Detailed experiences with patient adherence and behavioral adverse events.
- Which drug provides quality of life according to Neuro Physicians.
- To collect insights about highest selling brand of Brivaracetam and Levetiracetam.

3.Data analysis.

The data collected during research was analyzed using MS Excel. It conducted an analysis that enabled a better understanding of the quantitative findings by showing how Neuro Physicians and pharmacists perceive Brivaracetam/Levetiracetam, highlighting their preferences and attitudes towards these drugs.

4.triangulation

To ensure reliability and validity of this study, qualitative phase findings have been compared to quantitative results.

Data Analysis:

Therefore, it was important to analyze that data to get better results.

Quantitative Data Analysis

We entered the quantitative structured summaries into Microsoft Excel. Prepare graphics like bar chart, pie-charts graphs, histograms where one can easily figure out the substantial difference between Brivaracetam- Levetiracetam.

Qualitative Data Analysis:

Methodology: The data were analyzed with thematic analysis for the qualitative data from the in-depth interviews. Themes and patterns that emerged in the interview transcripts were examined over multiple reads. We sorted the most important aspects in order to break down why people felt and thought what they did. The thematic analysis provided in-depth understanding of the quantitative data collected and thus revealed the most depth-rich content alongside with the overall findings of the study.

Ethical Considerations

Taking the ethical issues into account, we handled responsibly throughout the steps taken in this study to ensure its legitimacy, and ethic process.

Informed Consent:

Participants were recruited through flyer advertisements and a university mass email list, and the study PI also gave brief presentations in large undergraduate classes at the university about the project; all participants received study information detailing what was required to participate (i.e., procedures and potential risks/benefits). Each participant had their own consent to participate in this research. This ensure that participants are aware of this study.

Confidentiality:

Information of participant is confidential. We removed name of participants name from the data. Data is secured. Published results are without participants information and in the form of graphs and charts.

Ethical Approval:

This research confirmed that it does not harm any participants.

Data Integrity:

Care of data was taken care to ensure accuracy and integrity of data. Errors and duplicates are removed before analysis process. Methodology and results are transparent which enhance this research.

Research Question

Questions for Neuro Physicians

- Q1. for newly diagnosed focal epilepsy patients, Which AED do you prefer to prescribe for newly diagnosed focal epilepsy patients?
- Q2. which drug has shown better efficacy in controlling seizures in your clinical experience, which drug has shown better efficacy in controlling seizures?
- Q3. How is patient compliance and adherence to Brivaracetam compared to Levetiracetam?
- Q4. In your practice, which drug has resulted in fewer reports of behavioral side effects from patients?
- Q.5 Overall, which antiepileptic drug do you believe provides better quality of life for your patients?

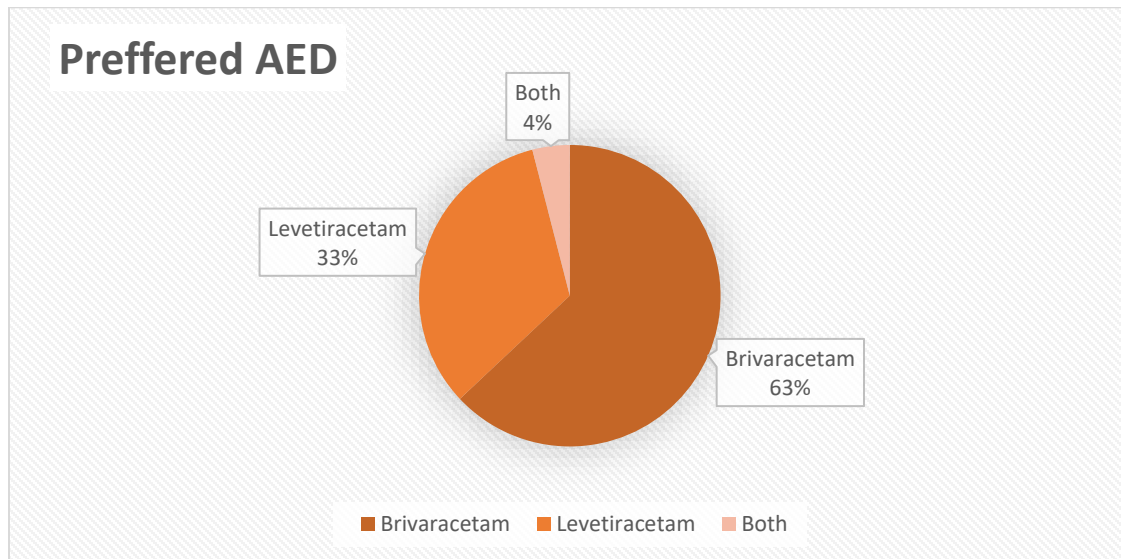
Questions for RCPA Activity

- Q1. Which is the top selling brand of Brivaracetam?
- Q2. Which is the top selling brand of Brivaracetam Levetiracetam?

Results

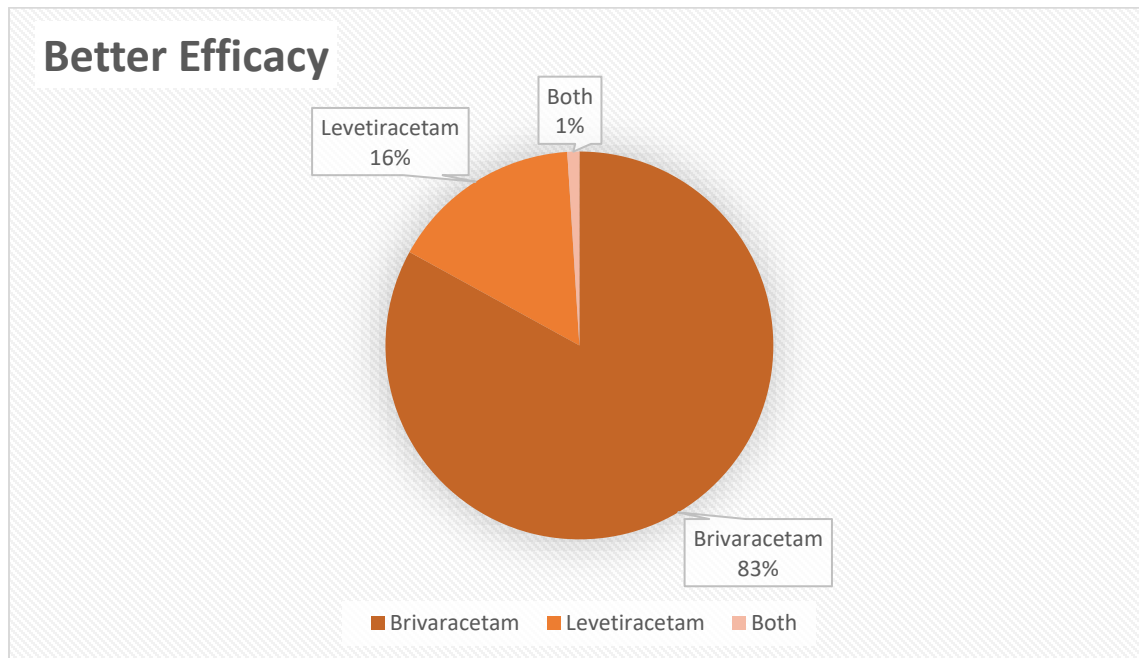
Results of Neuro Physicians questionnaire

Q1. For newly diagnosed focal epilepsy patients, Which AED do you prefer to prescribe for newly diagnosed focal epilepsy patients? (fig 4.1)



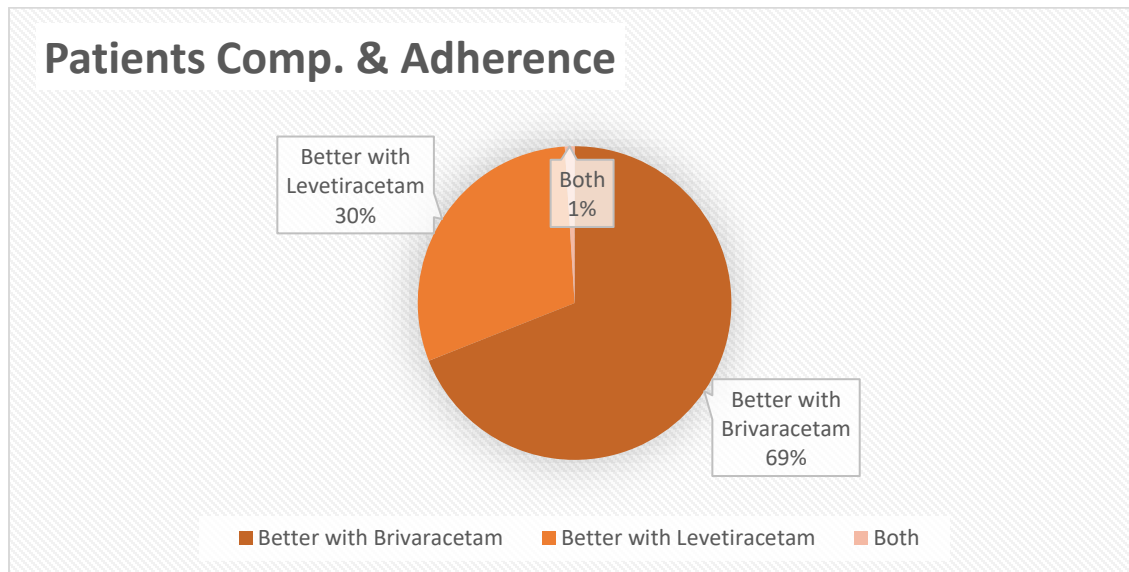
The survey results also showed that a majority (63%) of Neuro Physicians would be more likely to prescribe Brivaracetam in newly diagnosed focal epilepsy. This reflects a heavy preference for Brivaracetam compared to Levetiracetam (preferred by 33% of respondents). Approximately an eighth of Neuro Physicians prescribed about the same amounts of both drugs (4% of all EMR response pairs), As such, this should be considered a reflection of the everyday thinking of Neuro Physicians on what to use with what when it comes to treating newly diagnosed focal epilepsy.

Q2. Which drug has shown better efficacy in controlling seizures in your clinical experience (fig 4.2)



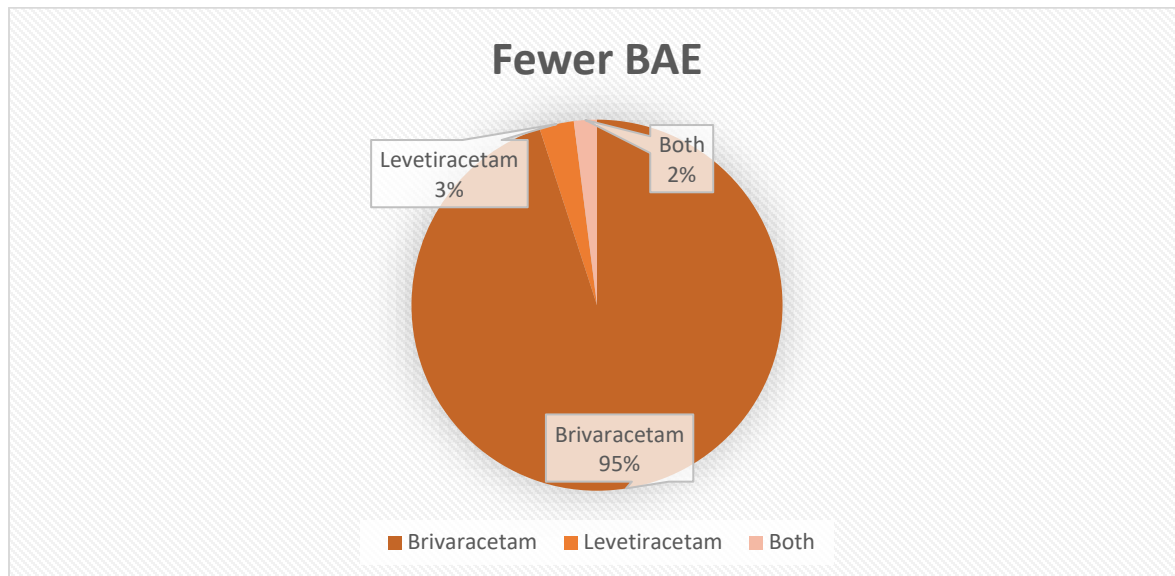
Most Neuro Physicians (83 %) stated the drug in their experience leads to the highest control over seizures was Brivaracetam when asked. 16% found Levetiracetam better and 1% felt no difference in efficacy. This additional strong preference in favor of Brivaracetam suggests that, in terms of seizure control efficacy, as seen in the perception of most referral health care workers, it is likelier to be efficacious and a superior rescue option.

Q3. How is patient compliance and adherence to Brivaracetam compared to Levetiracetam? (fig 4.3)



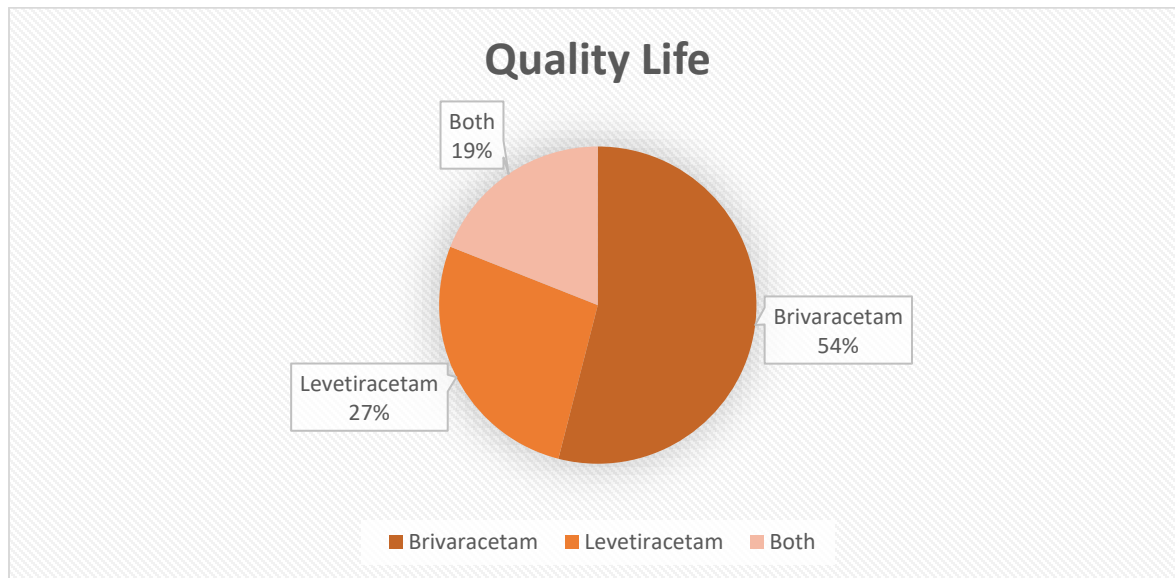
For the management of epilepsy it is very important that patient comply and adherant to treatment. Furthermore, 69 percent of Neuro Physicians think Brivaracetam demonstrates superior patient compliance and adherence when compared to Levetiracetam as described in the survey results. However, 30% of respondents thought patient adherence was higher with Levetiracetam. A mere 1% of all Neuro Physicians thought that the adherence rates of these two drugs were equal. This would suggest that Brivaracetam is generally thought to have a higher rate of patient adherence or compliance - whether this is due to fewer side effects, easier dosing schedules or better overall tolerability.

Q4. In your practice, which drug has resulted in fewer reports of behavioral side effects from patients? (fig. 4.4)



They noted, however, that these behavioral side effects could impair a patient's quality of life and compliance with medication. Overall Neuro Physicians reported that Brivaracetam led to significantly fewer behavioral side effects compared to Levetiracetam (95% of the field survey). Only 3% of participants thought that Levetiracetam was less likely to cause behavioral side effects and 2.5% that they had similar behavior profiles. This marked contrast implies that Brivaracetam is far less troublesome in its behavioral side effects, thereby more suited to chronic use.

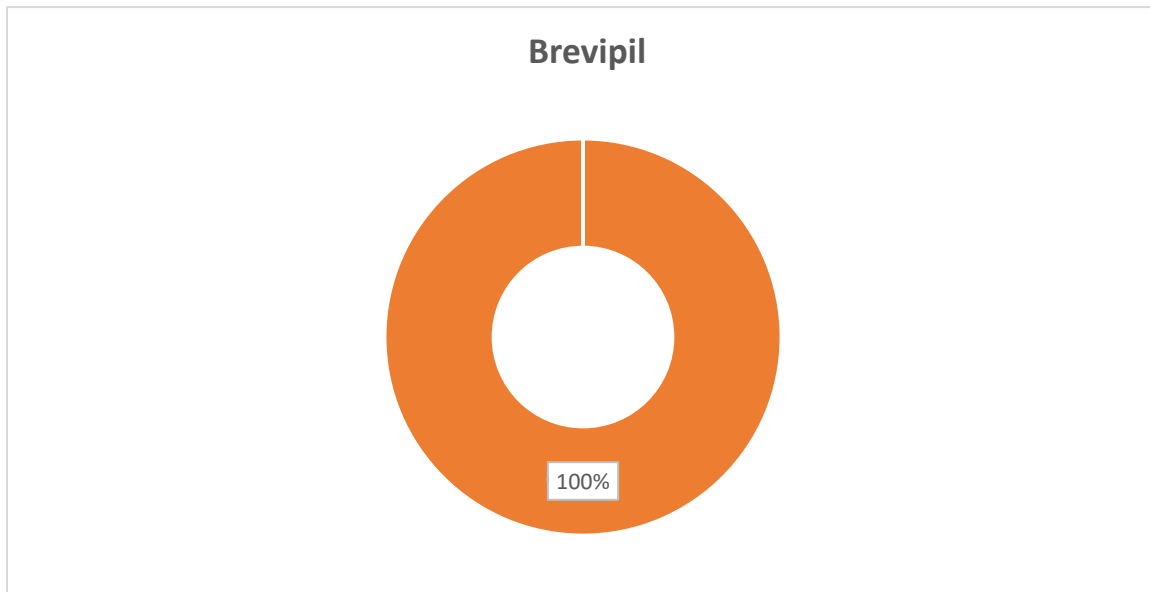
Q5. Overall, which antiepileptic drug do you believe provides better quality of life for your patients? (fig. 4.5)



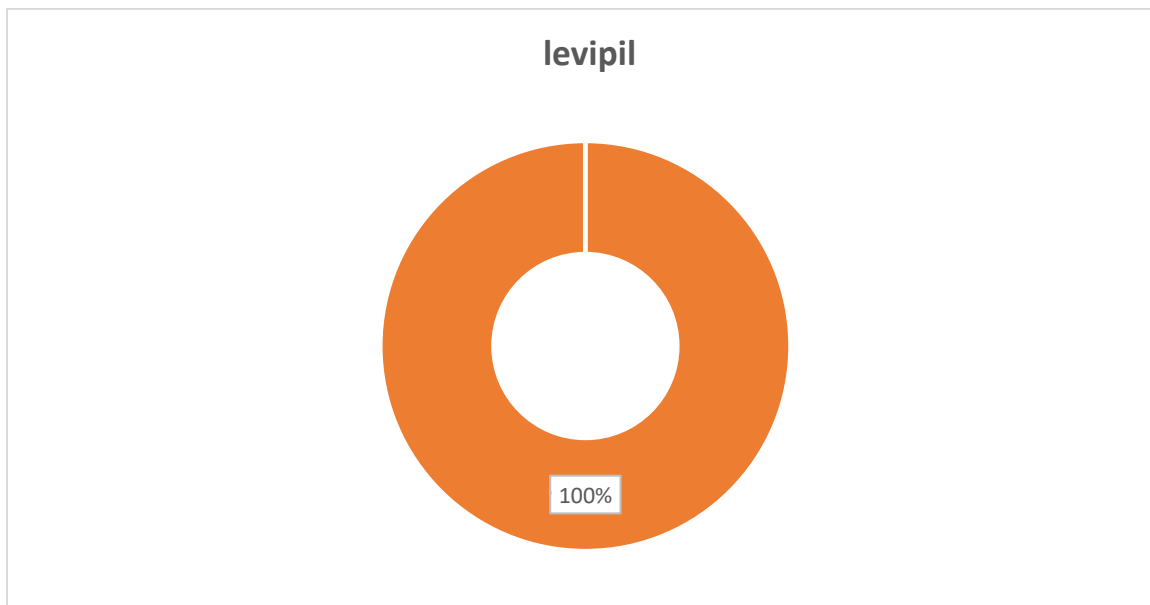
Overall, 54% of the surveyed Neuro Physicians felt that Brivaracetam improves the quality of life for patients versus 27% for Levetiracetam. Interestingly, 19% of Neuro Physicians believed that either drug provided equal patient quality of life. Which means that overall, Brivaracetam enjoys certain advantages over Levetiracetam but still a sizable contingent of prescribers sees significant benefits of Levetiracetam or consider them more or less equivalent.

Results of RCPA Activity

Q. Which is the top selling brand of Brivaracetam? (fig.4.6)



Q2. Which is the top selling brand of Levetiracetam? (fig.4.7)



Brivaracetam (neurological agent) and levetiracetam (anti-epileptic); both help control type of seizure in epilepsy. Brevipil - It Leads the Market with Brand for Brivaracetam and Levipil Tops

the List for Levetiracetam. Sun Pharmaceuticals is the largest selling company of these medicines and they are manufactured by two Sun Pharmaceutical brands. Sun Pharmaceuticals is ranked at the very top in both the Brivaracetam and Levetiracetam markets, with an impressive sales volume to their brand name as well.

Conclusion

The study was done to evaluate the preferences and perceptions of doctors with respect to drug molecules of two commonly used anti-epileptic drugs (AEDs) Brivaracetam and Levetiracetam in order to understand which antiepileptic drug is more favoured and why. The data from the survey of Neuro Physicians give a broad picture of current practices and preferences for treatment of patients with focal epilepsy as they begin newly diagnosed therapy.

Obviously, this points to a much stronger lean towards Brivaracetam by the Doctors. Brivaracetam is the most preferred drug by a majority (63%) of Neuro Physicians for new onset focal epilepsy while Levetiracetam is the next choice (33%). A mere 4% write for both drugs the same number of times. Reinforcing this preference 83% of Neuro Physicians feel Brivaracetam is more effective for controlling seizures versus 16% who would choose Levetiracetam. This pronounced preference also indicates that there is perceived clinical benefit of Brivaracetam over other treatment choices.

Good patient compliance and adhere to therapy is very important for successful treatment strategy. According to the study, 69% of Neuro Physicians believe patients have better adherence on Brivaracetam) than they did with Levetiracetam (30%). Neuro Physicians who believed the adherence rates between the two drugs were equal: 1% only This might imply that Brivaracetam is simply better tolerated with less side effects, easier do sotherapy or generally much less side-routine that brings about the conformity of the patients to be higher.

Behavioral side effects pose a significant effect on a patient's quality of life and his drug adherence. According to the study, 95% of Neuro Physicians said fewer behavioral side effects were reported by their patients when compared with levetiracetam. One respondent chose Levetiracetam with less behavioural side effects (3%) and two percent judged both being similar in terms of behavioural side effect. It is therefore a more attractive treatment to use for long term therapy as it would appear much better tolerated in an overwhelming majority of people.

Among Neuro Physicians, 54% said Brivaracetam gives patients a better quality of life, compared with 27% who chose Levetiracetam when taking into account the complete QOL responses. Seventeen percent of the doctors choose one over the other by its strength in one aspect or another, and 19% would call them even. This may reflect the general perception that

Brivaracetam delivers greater overall benefits, but also shows that a significant proportion of healthcare providers still see distinct advantages with Levetiracetam or judge the two drugs to be equally effective.

The study also featured pharmacy data that revealed the bestselling brands of Brivaracetam and Levetiracetam according to pharmacists. The brand of Brivaracetam which is sold at the highest in demand was Brevipil, and for Levetiracetam, Levipil are sold most according to the pharmacist. So, which of these two brands will be available in the market and they both are from Sun Pharmaceuticals. It appears that this knowledge based on market trends support the survey of Neuro Physicians and indicate a distinct commercial success and wide-spread acceptance of these specific brands.

It is further supported by the study that Brivaracetam took precedence over Levetiracetam, among the two antiepileptic drugs (AEDs), for observing the treatment of patients with newly diagnosed focal epilepsy from Neuro Physicians perspective. This preference seems to stem from beliefs regarding better effectiveness, greater patient compliance and less side effects that impair the performance of activities of daily living (ADLs) by improving patients' quality of life. The results provide some insight to aid in clinical-decision making for the future to optimize treatment of patients with epilepsy. Results published from this research provide key data that healthcare providers, pharmaceutical companies, and policy makers can use to tailor their approaches for managing epilepsy in order to improve care for patients.

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