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Original Article

Evaluation Of Effective Commercial Brands Of Sodium Valproate (Depaken) Drug Brands Sold In Pharmacies in Libya. A Prospective Study

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ABSTRACT:

Background*:* In Libya, there are a lot of different brands of Sodium Valproate (Depaken) tablets available from different international companies. The current study aims , to evaluate commercial brands of sodium Valproate (Depaken) drug sold in pharmacies in Libya. **Materials and Methods:** In this prospective revaluation study, a total of 40 cases (30-80) were patients who purchased Sodium Valproate drug with a label strength of 500 mg from two different brands of private pharmacies in Libya. Period from **January 2023** to **May 2023**.
The products were coded as A and B. This prospective study was conducted over 5 months. **Conclusion:** Our findings in this study, all brands of Sodium Valproate drug available in local pharmacies in Libya complied with international standards and can be interchangeable, while there was no significant variation in the effective rate of the drug, it can be inferred that the brands of Sodium Valproate drug are Commercial Brands equivalent.

Keywords: Sodium Valproate, Drug, Brands, pharmacies, Libya

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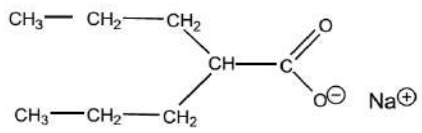
INTRODUCTION:

In Libya, there are a lot of different brands of Sodium Valproate (Depaken)tablets available from different international companies. Each brand has its own formulation, which affects the release and release of the drug and produce changeable clinical responses. Assessment of *in vitro* release and the physicochemical properties of these brands is very important as it can be used to assess the bioavailability and pharmaceutical correspondence [1]. The Tablets are oral solid unit dosage forms containing a blend of active medical substances in combination with suitable recipients, which are added to give desired properties that influence their effectiveness and stability [2]. Tablet recipients must be well-matched with each other and with the drug, and must improve tablet stability and pharmaceutical quality. Coated tablets are tablets coated with an inert substance that resists disbanding in gastric juice, but freely dissolves and liberates the drug in the intestines. [2, 3]. After oral administration of drugs, it may have unproductive drug absorption due to improper dissolution rather than absorbed rapidly and completely into the bloodstream [4]. Various brands available in the market are considered pharmaceutically equivalent if they contain the same amount of active ingredients in the identical dosage form and meet the same compendia standards in strength, quality, purity, and identity, but may differ in shape, packaging, recipients, expiration time, and labeling necessities [5]. According to the World Health Organization (WHO) the prevalence of fake medicines was higher in developing countries with weak regulations, enforcement, and scarcity of supply of essential medicines, unregulated market, and unaffordable prices [**6**]. For these reasons, the safety, quality, and efficacy of drug products especially in developing counties cannot be granted, therefore post market qualitative studies are important, few drug quality control.

Valproate sodium is the sodium salt of valproic acid designated as sodium 2-propylpentanoate. Valproate sodium has the following structure:



Depaken exists as the valproate ion in the blood. The mechanisms by which valproate exerts its therapeutic effects have not been established. It has been suggested that its activity in epilepsy is related to increased brain concentrations of gamma-aminobutyric acid (GABA).

The dosage of Depaken starts with 200 mg 2 times daily. Increase if necessary until the optimal dose for the individual patient is reached, usually around 500 mg 2 times daily [7]. Quality control is a practice or set of procedures intended to ensure that an artificial product complies with specifications. Quality control has an important role in pharmaceutical pasture, it's an examination applied to drugs and drug product, including all those factors which supply directly or indirectly to the safety, effectiveness, and reliability of the product . Patient safety is the most guiding value in all drug factories; the basic objective is to provide efficient, safe, and compatible products for the prevention and treatment of sickness. It's important to promote health and quality of life with the product by distributing guidance between consumers and healthcare professionals on the exact proper use and storage of the products [8].

Study objective:

This study was conducted to evaluate the quality of sodium Valproate (Depaken) tablets available in private pharmacies in Surman City in Libya.

We need timely and effective treatment that has a positive and fast effect and, at the same time, does not raise concerns about abuse. Therefore, this study aimed to evaluate the quality of sodium Valproate (Depaken) drugs to manage pain in patients who used sodium Valproate drugs.

MATERIAL AND METHOD.

Study Design:

This was a prospective evaluation Of Effective Commercial Brands of Sodium Valproate (Depaken) Drug Brands Sold in Pharmacies in Libya.

The period from *January 2023 to May 2023]*, Patients purchased Sodium Valproate drug with a label strength of 500 mg from two different brands from private pharmacies in Libya. The products were coded as A and B, and the study was performed within product expiration dates. Data were 40 cases collected by studying from public pharmacies in Libya, and patient recording logs over the five-month study period. Exclusion criteria were patients younger than 15 years old. The patients were selected by prescript from a general physician after physical examination by a neurologist and met the eligibility criteria and were recruited for the study. Information was gathered about the patient's medical history ,such as pulmonary, cardiac or cerebrovascular disease, diabetes, hypertension, any malignancy, medication intoxications and height and body weight.

Pulmonary disease was defined as any illness of the lungs or respiratory system, such as asthma, lung cancer, chronic infections, previous pulmonary embolisms, or chronic obstructive pulmonary disease. Cardiac disease refers to coronary artery disease with or without previous intervention, heart failure, arrhythmias, valvular heart disease or cardiomyopathy.

STATISTICAL ANALYSIS:

These were performed with SPSS 20.0 software (**SPSS Institute**). Student ***t*-test** was used in the analysis of parametric data and results were presented as mean (**SD**) or mean (standard error of means). The analysis of categorical data was performed with the two-tailed Pearson chi-square test and the results were expressed as numbers. A *P*-value less than (0.05) was considered statistically significant.

RESULTS:

Table 1 Demographic Characteristics of the Study**.**

CHARACTERISTICS	SODIUM VALPROATE (n=%)
Age	33.9±9.5
Gender Male	9 (22.5)
Female	31 (77.5)
Level of education	
Illiterate	2 (5.0)
Elementary	6 (15.0)
Under diploma	12 (30.0)
Diploma	13 (32.5)
Collage education	7 (17.5)
Duration of disease (yr)	
1-2	1 (2.5)
3-5	17(42.5)
>5	22 (55)
Time from onset (m)	
≤1	0
1-6	14 (35.0)
6-12	19 (47.5)
12-24	7 (17.5)

% Percentage. n = number of patients

A total of 40 patients were enrolled and analyzed. All of these patients continued follow-up. There were 31 women and 9 men (mean age, 33.38±9.15 years) who used different Commercial Brands. The patient's demographic information is shown in Table 1. There were no significant differences in demographic features in Table 1.

Table 2. The effect of Commercial Brands of drugs on associated symptoms:

Symptoms	Brand A	Brand B
	Number of Patients (Improved %)	Number of Patients (Improved %)
Photophobia	20 (50%)	21 (52.5%)
Phonophobia	17 (42.5%)	16 (40%)
Nausea	28 (70%)	23 (57.5%)
Vomiting	9 (22.5%)	10 (25%)

, %

Percentage. n = number of patients

Table 2 depicts the rate of improvement in the effect of commercial brands of drugs-associated with symptoms in the two
brands and a comparison of these improvement rates between the two groups. According to this table, photophobia, phonophobia, nausea, and vomiting were improved in the two ciated symptom while only nausea was significantly in brand A, denoting the advantage of Brand A in improving associated symptoms

Figure 1: Revaluation of Commercial Brands of drugs at similar time points according to repeated measure ANOVA test.

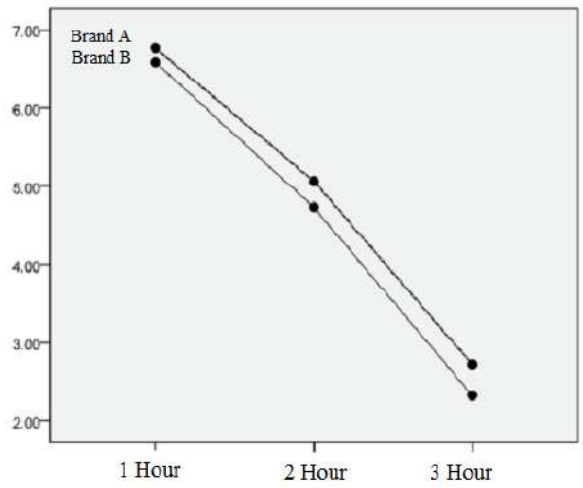


Figure 1 demonstrates a comparison between the two Commercial brand drugs at the mentioned time points using the repeated-measure ANOVA test. Comparing these effective rates in both Brands at similar time points showed no significant difference.

Figure 2: The Percentage of Feeling Patients Achieving Reduction in Symptom Score between Two Commercial Brands of Drugs.

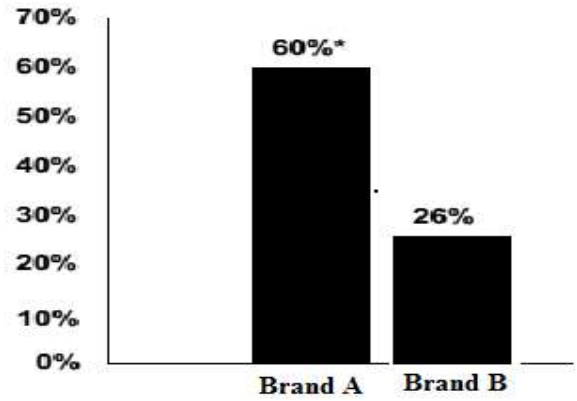


Figure 2 shows the Percentage of achieving ≥31% Reduction in Symptom Score ,according to feeling patients, during the treatment phase no differences in baseline effective rates.

DISCUSSION:

One of the many acceptable drugs for neurological treatment, this randomized demonstrated that sodium valproate effectively treated acute disease. More patients in the Commercial Brand A than Commercial Brand B of the sodium valproate group recovered, but the difference was not statistically significant. In other words, the drugs demonstrated the same efficacy for treatment. Similar studies performed in Iran during 2013 and 2015 showed that the two drugs had the same effects on headache relief [9]. In the present study, the headache relief rates in the sodium valproate and dexamethasone groups were 55% and 67.5% in the first 0.5 hour, respectively.

In other studies, the percentage of pain relief after 1 hour in patients receiving sodium valproate was reported as 25%39 and 53.3%.28 There was no significant association between the two groups in terms of demographic factors and recovery rate in the first 0.5 hour.

Foroughipour et al.[10] reported the duration of headache relief in the sodium valproate and dexamethasone groups as 292 and 270 minutes in 26% and 33% of patients, respectively. In that study, the sample size was small, and the patients received therapeutic dosages higher than those used in our study. Unfortunately, the therapeutic dosage of sodium valproate for acute migraine headache has yet to be determined. In several studies, the therapeutic dosage of valproate was variable (400 to 1,200 mg), and the drug was diluted in normal saline (50 to 200 mL) [11]. In another study, both drugs were administered in a single dose diluted in a small amount of normal saline (4 mL) to avoid a confounding effect of normal saline, which is able to reduce headache via hydration.10,40 Limdi et al.[12] reported the safety of a rapid infusion of undiluted sodium valproate in the treatment of epilepsy.

Bakhshayesh et al.[13] reported that sodium valproate was more effective than metoclopramide and sumatriptan at providing headache relief during the 2 hours post-treatment, whereas Rahimdel et al.[14] reported that intravenous sodium valproate and subcutaneous sumatriptan have similar abilities to control acute attacks. Edwards et al. [14] reported equal effectiveness in headache improvement after treatment with sodium valproate compared with dihydroergotamine and metoclopramide.

Tanen et al [15]. Compared the efficacy of intravenous sodium valproate versus prochlorperazine and demonstrated that the former was less effective at decreasing pain or nausea; however, patients were followed for the first hour and also received rescue therapy, which is a confounding variable.

CONCLUSION:

In this study, all brands of Sodium Valproate drug available in local pharmacies in Libya complied with international standards and can be interchangeable, while there was no significant variation in the effective rate of the drug, it can be inferred that the brands of Sodium Valproate drug are Commercial Brands equivalent. This study highlights the need for focusing on changing the feelings of patients' evaluation of Commercial Brands products circulating in the markets originating from different manufacturers, especially in Libya country.

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