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Original Research Article

Comparative Study of Efficacy of Itopride versus Levosulpiride Used Orally in Patients Suffering From Non-Ulcer Dyspepsia – Retrospective Study

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Abstract:

Background: Dyspepsia is a clinical problem with many manifestations, such as belching, heartburn, anorexia, nausea, and vomiting. Proper medication is necessary; hence, an ideal prokinetic drug has to be studied with a comparison of the efficacy of both drugs.

Method: Out of 90 patients with dyspepsia, 45 patients were treated with Itopride and 45 with Levosulpiride, and their efficacy was compared.

Results: More relief was observed in the Itopride group 28 (62%) compared to the 22 (48.8%) group of Levosulpiride. Moderate relief was highest in Itopride 15 (33.3%) and 14 (31%); in Levosulpiride, worsening of the symptoms was observed only in Levosulpiride 1 (2.22%). The comparison of serum biochemistry and Q.T interval of both drugs has a significant p-value ($p < 0.001$). The side effect of diarrhea was 2 (4.4%) in levosulpiride, while headache was 3 (6.6%) in Itopride.

Conclusion: Both levosulpiride and Itopride were equally effective and well-tolerated in treating the symptoms of non-ulcer dyspepsia.

Keywords: Dyspepsia, Itopride, Levosulpiride, Endoscopy.

Introduction

Functional dyspepsia, also called non-ulcer dyspepsia, is a chronic disorder of the gastro-duodenum and a disorder of gut-brain interactions [1]. The condition is diagnosed using the Rome IV criteria, which includes epigastric pain or burning, early satiety, and/or postprandial fullness in the presence of a structurally normal upper gastrointestinal endoscopy [2].

About 25% of cases with dyspepsia symptoms have an underlying organic lesion in the upper gastroduodenal area, gallbladder, or intestine, which is termed organic dyspepsia.

However, about 75% of cases with dyspeptic symptoms don't show any underlying lesion and are grouped as functional dyspepsia [3]. It was also reported that symptoms could be pooled into four subgroups to reflect their most likely underlying pathophysiology, thereby guiding clinicians in their choice of therapy. The subgroups are classified as reflux-like, ulcer-like, dysmotility-like, and unspecified (non-specified) dyspepsia. Symptoms like bloating, belching, heartburn, and pain relief with defecation may overlap [4]. Hence, two drugs were chosen to rule out the efficiency of non-ulcer dyspepsia, and the pros and cons of both drugs were compared.

Material and Method

90 (ninety) adult patients regularly visited Moopen's Medical College hospital, Wayanad, Kerala-673575, and were studied.

Inclusion Criteria: The patients above 18 years having complaints of non-ulcer dyspepsia like epigastric distention or pain, nausea, or heartburn for at least 10-12 weeks. The patients who gave their consent for the study in writing were selected for the study.

Exclusion Criteria: Patients under 18 years of age, pregnant and lactating mothers, patients with ulcers and severe esophagitis, and patients on antidiabetic medication were excluded from the study.

Method: Out of 90 patients, patients were randomly allocated into two groups, 45 in each group. Group I (number 45) patients received one tablet of Itopride hydrochloride 50 mg three times daily before meals for two weeks.

Group II (number 45) patients received one Levosulpiride 75 mg tablet three times daily before meals for two weeks and continued up to three months if needed. Concomitant medication with any other prokinetic drugs, antacids, enzyme preparations, H2 blockers, or proton pump inhibitors was not permitted during the study. The grading of response was marked as complete relief, moderate relief, slight relief, no relief, and worsening of symptoms in both groups.

The duration of the study was from January 2023 to July 2023.

Statistical Analysis: Response to the treatment in both drugs was classified with a percentage. The comparison of the effect of therapy on serum biochemical and Q-T interval was studied in both groups (pre- and post-treatment) by applying the ANOVA test.

The ratio of male and female was 2:1.

Observation and Results

Table 1: Study of response of treatment in patients with non-ulcer dyspepsia

- Marked or complete relief: 28 (62.2%) in group-I, 22 (48.8%) in group-II and p<0.005.
- Moderate relief: 15 (33.3%) in group-I, 14 (31.1%) in group-II.
- Slight relief: 2 (4.4%) in group-I, 6 (3.3%) in group-II
- No relief: zero in group-I, 1 (2.2%) in group-II

Table 2: Comparative study of the effect of therapy on serum Biochemistry and QT internal

- Hb%: In group-I: pre 12.5 2 (± 1.60), 12.1 (± 2.0) in post. Group-II 11.8 (± 2.02) in pre, 11.5 (± 1.88) in post, F=32.94 and p<0.001
- FBS: In group-I: 82.4 (± 1150) in pretreatment, 85.2 (± 8.20) in post. Group-II 82.8 (± 9.80i) in post, 83.8 (± 8.72) in pre, DF 174.5 and p<0.005.
- WBC (cum): In group-I 87.64 (± 24.02) in pretreatment, 86.24 (± 20.65) in post. In group-II 82.24 (± 22.48) in pre, 22.49 (± 23.45) in post, DF=1.648 and p<0.001.
- BUN: In group-I 8.6 (± 1.38) in pretreatment, 8.8 (± 1.18) in post. In group-II 8.4 (± 1.50) in pre, 9.2 (± 2.02) in post, DF=2.172 and p<0.001.
- Creatinine: In group-I 8.82 (± 0.13) in pretreatment, 0.84 (± 0.11) in post. In group-II 0.73 (± 0.15) in pre, 0.76 (± 0.14) in post, DF=6.646 and p<0.001.
- AST (unit/L): In group-I 28.2 (± 9.40) in pretreatment, 28.1 (± 10.6) in post. In group-II 26.5 (± 8.90) in pre, 24.1 (± 6.80) in post, DF=2.02 and p<0.002.
- ALT (unit/L): In group-I 31.3 (± 8.20) in pretreatment, 30.2 (± 4.30) in post. In group-II 31.8 (± 7.90) in pre, 30.8 (± 6.9) in post, DF=5.05 and p<0.001.
- G.G.T (units): In group-I 31.65 (± 10.6) in pretreatment, 34.2 (± 9.70) in post. In group-II 25.5 (± 2.40) in pre, 27.4 (±13.9) in post, DF=5.05 and p<0.001.
- ALP (units/ml): In group-I 136.4 (± 18.62) in pretreatment, 144.4 (± 19.50) in post. In group-II 135.2 (± 25.8) in pre, 130.2 (± 32.09) in post, DF=2.574 and p<0.001.
- Bilirubin: In group-I 0.94 (± 0.2) in pretreatment, 0.93 (± 0.3) in post. In group-II 0.96 (± 0.2) in pre, 0.83 (± 0.2) in post, DF=2.886 and p<0.001.
- Total cholesterol (mg/dl): In group-I 168.2 (± 40.6) in pretreatment, 164.3 (± 30.8) in post. In group-II 169.4 (± 31.60) in pre, 163.2 (± 25.50) in post, DF=1.379 and p<0.001.
- QT interval: In group-I 0.33 (± 0.048) in pretreatment, 0.32 (± 0.04) in post. In group-II 0.46 (± 0.01) in pre, 0.48 (± 0.05) in post, DF=5.44 and p<0.001.

Table 1: Response of treatment in patients with non-ulcer dyspepsia

Response	Group-I (Itopride 45)	Group-II (Levosulpiride 45)	p value
Marked or complete relief	28 (62.2%)	22 (48.8%)	P<0.005
Moderate relief	15 (33.3%)	14 (31.1%)	
Slight relief	2 (4.4%)	6 (3.3%)	
No relief	0	2 (4.4%)	
Worsening of symptoms	0	1 (2.2%)	
Total	45	45	

P<0.005 (p-value is highly significant)

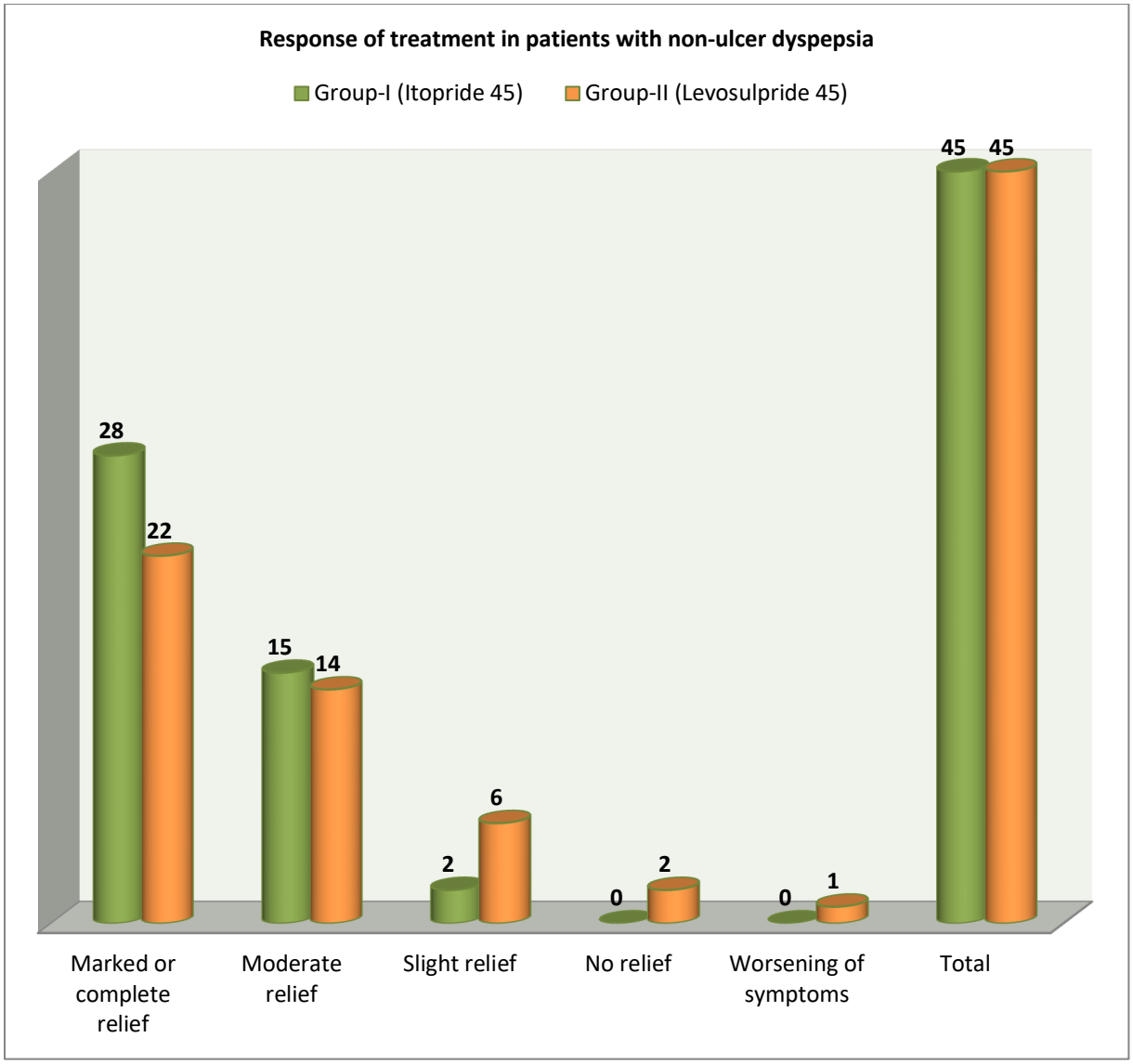

Figure 1: Response of treatment in patients with non-ulcer dyspepsia

Table 2: Comparison of the effect of therapy on serum Biochemistry and QT interval (ANOVA TEST)

Parameters	Group-I Itopride (45)		Group-II Levosulpiride (45)		p value
	Pre-treatment	Post-treatment	Pre-treatment	Post-treatment	
Hb (mg/dl)	12.5 (± 1.4)	12.1 (±2.01)	11.8 (±2.02)	11.5 (±1.88)	P<0.001
FBS (mg/dl)	82.4 (±11.50)	85.2 (± 8.20)	82.3 (± 9.80)	83.8 (± 8.72)	P<0.005
WBC-TCC/cum	87.69 (± 24.02)	86.24 (±20.62)	82.24 (± 22.48)	82.49 (± 23.45)	P<0.001
BUN	8.6 (± 1.38)	8.8 (± 1.18)	8.4 (± 1.50)	9.2 (± 2.03)	P<0.001
Creatinina	0.82 (± 0.13)	0.84 (± 0.11)	0.73 (± 0.15)	0.76 (± 0.14)	P<0.001
AST (units/L)	28.2 (± 9.40)	28.1 (± 10.60)	26.5 (± 8.90)	24.1 (± 6.80)	P<0.005)
ALT (units/L)	31.3 (± 8.20)	30.2 (± 4.30)	31.8 (± 7.90)	30.8 (± 6.39)	P<0.001
Y-GT (units)	31.6 (±10.60)	34.2 (± 9.70)	25.5 (± 12.40)	27.4 (± 13.89	P<0.001
AIK-Phos. (units/ml)	136.4 (± 18.62)	144.4 (± 19.50)	135.2 (± 25.80)	130.2 (± 32.04)	P<0.001
Bilirubin (mg/dl)	0.94 (± 0.2)	0.93 (± 0.3)	0.96 (± 0.2)	0.83 (± 0.2)	P<0.001
Total cholesterol (mg/dl)	168.2 (± 40.62)	164.3 (± 30.8)	169.4 (±31.60)	163.2 (± 25.50)	P<0.005
QT-interval	0.33 (± 0.048)	0.32 (± 0.04)	0.46 (± 0.01)	0.48 (± 0.05)	P<0.001

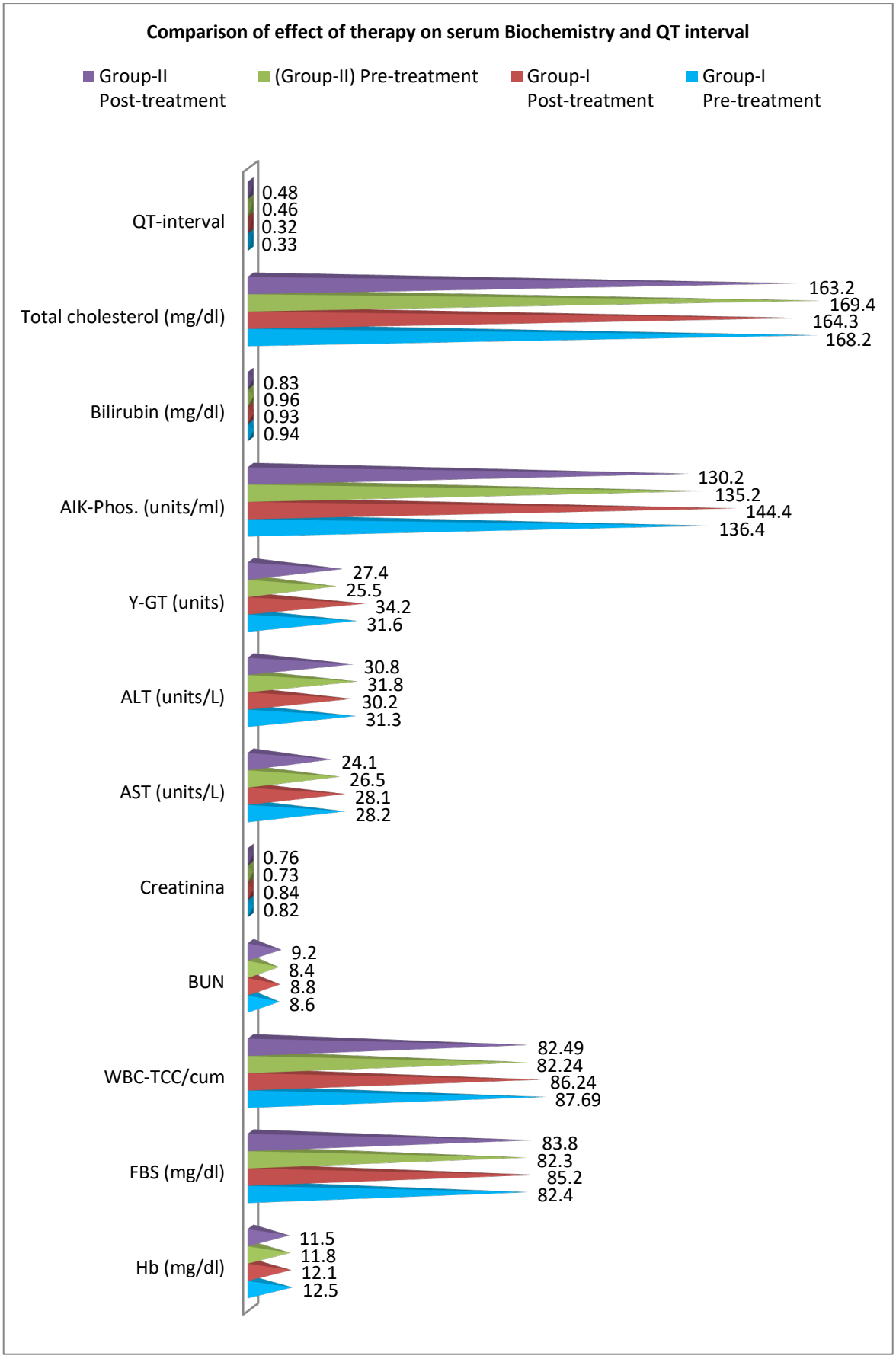

Figure 2: Comparison of effect of therapy on serum Biochemistry and QT interval

Table 3: Study of adverse effect of Therapy

Adverse effect	Group-I Itopride (45)	Group-II Levosulpiride (45)
Diarrhea	0	2 (4.4%)
Headache	3 (6.6%)	0

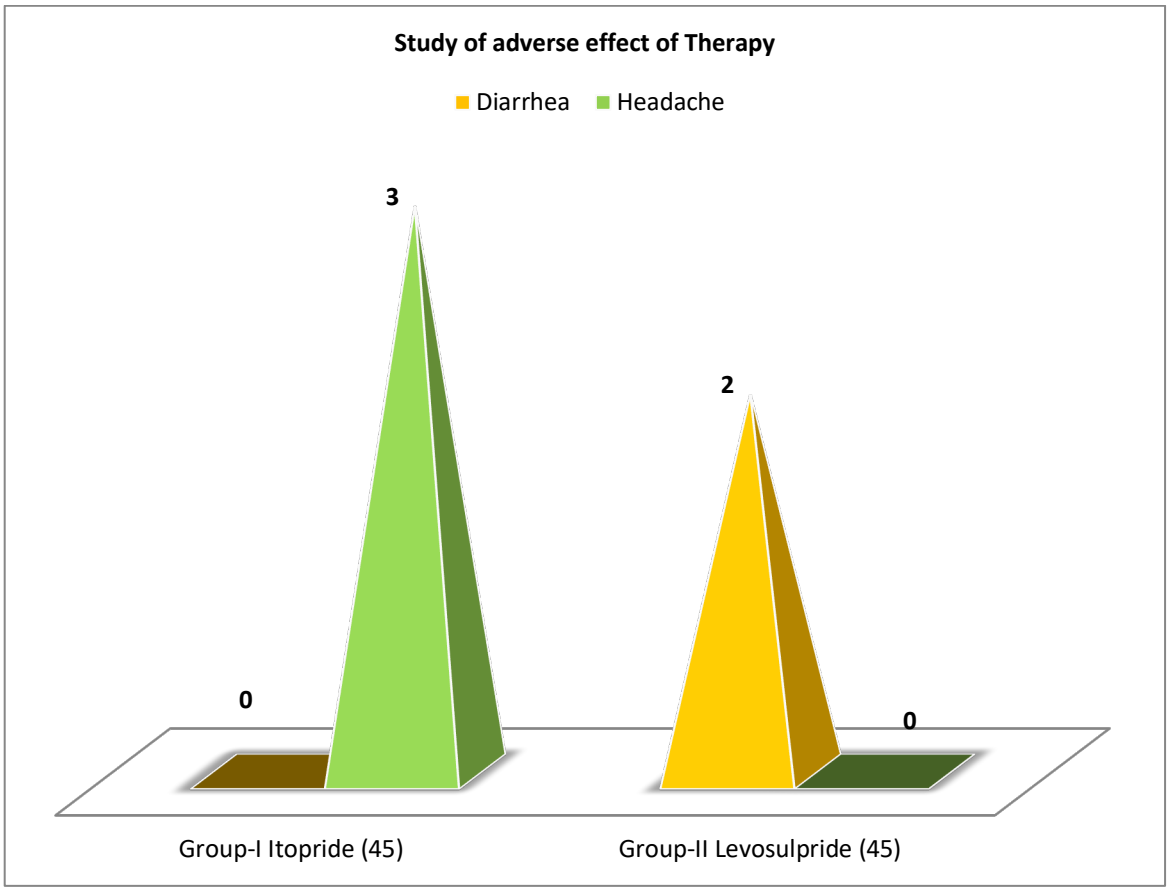

Figure 3: Study of adverse effect of Therapy

Discussion

Present a comparative study of the efficacy of Itopride versus Levosulpiride used orally in patients suffering from non-ulcer dyspepsia. In response to pre-treatment, the patients with non-ulcer dyspepsia in group I (Itopride) had the highest or complete relief, marked 28 (62.2%) compared to 22 (48.8%) in group II. The highest moderate relief was in group I (Itopride) with 15 (33.3%) patients, while 14 (31.1%) were in group II (Levosulpiride), with worsening symptoms in 1 (2.22%) in group II (Levosulpiride group) (Table 1). In the comparison of the effect of therapy on serum biochemistry and the Q-T interval in both groups, there was a significant p-value ($p<0.001$) (Table 2). The adverse effects of therapy group II (Levosulpiride) had diarrhea in 2 (4.4%) and 3 (6.6%) in headache in group I (headache) (Table 3). These findings are more or less in agreement with previous studies [5,6,7].

Functional dyspepsia is a common condition; symptomatic improvement after prokinetic drug therapy may be incomplete and obtained in about 60-80% of patients. The common symptoms were upper abdominal pain, epigastric burning, abdominal fullness, early satiety, and postprandial bloating, while fewer symptoms were belching, heartburn, and nausea [8]. It is also revealed that Cisapride, Domperidone, Omeprazole, and Tegaserod were associated with significant amelioration in functional dyspepsia symptoms compared with placebo [9]. New pharmacological therapies are being recommended as effective management for gastric emptying delay in people with functional dyspepsia. Novel prokinetics like Cisapride, Itopride, Domperidone, and proton pump inhibitors (PPI) are the mainstay of the treatment of functional dyspepsia; both have similar relative efficacy [10]. The underlying mechanism of symptoms is multifactorial, including visceral hypersensitivity, brain-gut interactions, and underlying psychological comorbidity; antidepressants have been recommended in functional dyspepsia [11].

Summary and Conclusion

The present study compares the efficacy of Itopride versus Levosulpiride in non-ulcer dyspepsia. Both prokinetics are equally efficient and tolerable. This

study demands that such clinical trials be carried out on a large number of patients in a high-tech hospital to confirm present findings. It is believed that improving living habits and psychological management benefits these patients. Commonly used routine therapies are prokinetics, eradication of Helicobacter pylori, serotonin agonistics, proton pump inhibitors, or even antidepressants. They are useful in functional dyspepsia because the exact pharmacological therapy is still unclear.

Limitation of study: Due to the research Centre's tertiary location, small number of patients, and lack of latest techniques, we have limited findings and results.

This research was approved by the ethical committee of Dr. Moopen's Medical College hospital Wayanad, Kerala-673575

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