

A COMPARATIVE STUDY ON RABEPRAZOLE WITH FLUPENTIXOL/MELITRACEN AND RABEPRAZOLE WITHOUT FLUPENTIXOL/MELITRACEN IN THE TREATMENT OF STRESS INDUCED EROSIIVE GASTROPATHY AND ITS OUTCOMES

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ABSTRACT

Introduction: The co-administration of PPIs and psychiatric drugs for the treatment of stress-induced erosive gastropathy has not received much attention. In order to close this knowledge gap, our study offers proof of the effectiveness and security of this kind of combination therapy. This study intends to improve patient outcomes, lessen the intensity of symptoms, and improve the quality of life for those with SIEG by treating both the physiological and psychosocial elements of the illness. Finding the best treatment plan can be accomplished by contrasting the results of rabeprazole monotherapy with rabeprazole in combination with flupentixol/melitracen. A deeper comprehension of various therapy methods may result in enhanced patient care, improved management techniques, and maybe lower medical expenses through more efficient care. **Methods and Material:** This was a observational cohort study conducted on 54 students at at Lalitha super specialties hospital, Guntur. Patients who visited the LSSH departments of general & minimally invasive surgery, general medicine (gastroenterology), and met the study requirements were included. Numerical pain rating was used to assess the change in pain after treatment, DASS21 scale was used to assess the change in stress after treatment, dyspnoea symptoms and adverse events were also assessed. **Results:** There are 32 male and 22 female patients total in the research. 46 patients in all had NPRS decreases, of which 85.71% were attributable to combination treatment and 84.61% to monotherapy. 40 patients in all had reduced stress levels; of these, 85.71% were attributable to combination treatment and 61.53% to monotherapy. 23 individuals in all had reduced dyspepsia symptoms, of which 46.42% were brought on by combination medication and 38.46% by monotherapy. More number of adverse events were found in patients treated with combination therapy. **Conclusion:** In summary, the combination of rabeprazole and flupentixol/melitracen is more successful in treating SIEG than rabeprazole monotherapy, even if it is still a safe alternative. To improve patient outcomes, clinicians should take into account this combination therapy, especially when stress and psychological variables are major contributors to the illness process.

KEYWORDS: Rabeprazole, Flupentixol, Melitracen, Stress-induced erosive gastropathy, Combination therapy, Symptom relief, Adverse events.

INTRODUCTION

An important gastrointestinal condition known as stress-induced erosive gastropathy is marked by inflammation and erosion of the stomach lining. Patients with high stress levels, such as those dealing with psychological stress, chronic sickness, or extreme physical stresses, are more likely to experience it. Finding efficient therapies is crucial to enhancing patient outcomes and standard of living. By lowering the production of stomach acid, proton pump inhibitors (PPIs) such as rabeprazole are

frequently used to treat erosive gastropathy. Nonetheless, since underlying stress is a major cause of SIEG, it is necessary to investigate supplementary therapies.^[1,2,3]

Melitracene and flupentixol are psychiatric drugs. Melitracen is a tricyclic antidepressant, while flupentixol is a thioxanthene antipsychotic having anxiolytic and antidepressant qualities. These medications have been combined to treat anxiety and depression, which are frequently linked to gastrointestinal issues brought on by

stress. Because rabeprazole and flupentixol/melitracen work together to address both the physiological and psychological aspects of the condition, there may be a chance for a more successful treatment for SIEG. Assessing the effectiveness of this combination in conjunction with rabeprazole may shed light on comprehensive treatment strategies that take into account both the physiological and psychological elements of SIEG.^[4,5,6]

Finding the best treatment plan can be accomplished by contrasting the results of rabeprazole monotherapy with rabeprazole in combination with flupentixol/melitracen. A deeper comprehension of various therapy methods may result in enhanced patient care, improved management techniques, and maybe lower medical expenses through more efficient care.^[7,8,9]

The co-administration of PPIs and psychiatric drugs for the treatment of stress-induced erosive gastropathy has not received much attention. In order to close this knowledge gap, our study offers proof of the effectiveness and security of this kind of combination therapy. This study intends to improve patient outcomes, lessen the intensity of symptoms, and improve the quality of life for those with SIEG by treating both the physiological and psychosocial elements of the illness.^[10,11]

AIM

To compare flupentixol/melitracen plus rabeprazole and rabeprazole as monotherapy with outcomes like patient satisfaction, impact on mental health and reducing clinical symptoms of stress induced erosive gastropathy.

OBJECTIVES

1. To evaluate the significance/effectiveness between the combination therapy & monotherapy in stress induced erosive gastropathy
2. To evaluate the effective treatment outcome in the patient.
3. To promote quality of life of patient.

METHODOLOGY

Ethical Approval: The study was initiated after the clearance of institutional ethics committee.

Study Site: The study was done only in outpatient wards of general & minimally invasive surgeries department in Lalitha super specialty hospitals, Guntur, 52001.

Study Duration: The study is conducted over a period of 6 months i.e. from (October 2022 to March 2023).

RESULTS

1. GENDER DISTRIBUTION

GENDER	COMBINATION THERAPY	MONOTHERAPY	TOTAL
MALE	17 (60.7%)	15 (57.7%)	32 (59.2%)
FEMALE	11 (39.3%)	11 (42.3%)	22 (40.7%)
TOTAL	n ₁ =28	n ₂ =26	N=54

Study Design: This is a observational, cohort study.

Sample Size: 54 patients were enrolled into this study.

Study method: Patients who visited the LSSH departments of general & minimally invasive surgery, general medicine (gastroenterology), and met the study requirements were included. Relevant information, including demographics, medical history, diagnosis, medication name, dosage, route, frequency, length of therapy, total number of pills taken daily, laboratory results, and allergy status, was gathered from the patient's medical records and, when necessary, through patient interviews. Any modifications to medication therapy were tracked and recorded on a daily basis. For use in the study, an appropriate data collecting form has been created. Keep an eye on the patient's potential allergic responses. Numerical pain rating was used to assess the change in pain after treatment, DASS21 scale was used to assess the change in stress after treatment, dyspnoea symptoms and adverse events were also assessed.

Study Criteria

Inclusion Criteria

- Both male and female patients of age between 18-60yrs, diagnosed with moderate to severe erosive gastropathy i.e. endoscopic evaluation caused by psychological stress showing the clinical presentation like dyspepsia, pain in upper abdomen, nausea/vomiting & having the DASS21 score >20 for stress especially.

Exclusion Criteria

- Male and Female patients less than 18yrs of age.
- Who has a social history of alcohol intake, smoking, & other substances like cocaine etc.
- Patients who has a past medical history of DM, HTN.
- Patients who were using the OTC drugs like NSAID'S & others like antihypertensive, antiarrhythmic, other class of PPI's etc. that reduces the acid secretions in stomach.
- Patients who were diagnosed with H. pylori.

Statistical Analysis

All the raw data was collected in google forms & viewed in excel sheet 2013 in WINDOWS 11, the statistical analysis was done in Microsoft excel 2013 by non-parametric chi square test for knowing P value.

The aforementioned data indicates that there are 17 males (60.7%) and 11 females (39.3%) receiving combination treatment. There are a total of 28 patients receiving combo treatment. There are 11 girls

(42.3%) and 15 males (57.7%) in single therapy. There are 26 patients in total in monotherapy. There are 32 male and 22 female patients total in the research (N=54).

2. NUMERICAL PAIN RATING SCALE (PAIN IN ABDOMEN)

NPRS	COMBINATION		MONOTHERAPY		TOTAL	P value (chi-square test)
	FREQ	PERCENT	FREQ	PERCENT		
Decreased	24	85.7142	22	84.6154	46	0.90957
Normal	4	14.2857	4	15.3846	8	
TOTAL	28	100	26	100	54	

The NPRS reports following combination and monotherapy treatments were shown in the above table. 46 patients in all had NPRS decreases, of which 85.71% were attributable to combination treatment and 84.61%

to monotherapy. Eight patients, of whom 14.28% were receiving combination medication and 15.38% were receiving monotherapy, reported no change in their abdominal discomfort.

3. DASS21 (Stress)

STRESS	COMBINATION		MONOTHERAPY		TOTAL	P value (chi-square test)
	FREQ	PERCENT	FREQ	PERCENT		
Decreased	24	85.7142	16	61.5384	40	0.04280763
Normal	4	14.2857	10	38.4615	14	
TOTAL	28	100	26	100	54	

The DASS21, in particular the stress reports following combination and monotherapy treatments, were displayed in the table. 40 patients in all had reduced stress levels; of these, 85.71% were attributable to

combination treatment and 61.53% to monotherapy. In 14 patients, with 14.28% receiving combination treatment and 38.46% receiving monotherapy, the stress levels were normal.

4. DYSPEPSIA

DYSPEPSIA	COMBINATION		MONOTHERAPY		TOTAL	P value (chi-square test)
	FREQ	PERCENT	FREQ	PERCENT		
Decreased	13	46.4286	10	38.4615	23	0.55413
Normal	15	53.5714	16	61.5385	31	
TOTAL	28	100	26	100	54	

The dyspepsia reports following combination and monotherapy treatments were shown in the table. 23 individuals in all had reduced dyspepsia symptoms, of which 46.42% were brought on by combination

medication and 38.46% by monotherapy. 31 patients had normal dyspepsia, of whom 15 were receiving combination medication and 16 were receiving monotherapy.

5. ADVERSE EFFECTS

ADVERSE EFFECT	COMBINATION	MONOTHERAPY
CONSTIPATION	1	0
DIARRHEA	1	2
DRY MOUTH	2	0
RESTLESSNESS	3	0

The above table depicts about the adverse effects, more number of adverse events were found in patients treated with combination therapy.

DISCUSSION

The current study examined the efficacy of combination and monotherapies in treating 54 SIEG patients. The DASS21 score of the patients in this study showed a decrease in stress, and symptoms such as dyspepsia and abdominal pain also decreased.

A total of 54 individuals were involved in our study; 28 of these patients got combination treatment, and they demonstrated a reduction in stress levels of 85.7% and 61.5% in monotherapy, respectively. Stress levels differ significantly ($p < 0.05$) between combination and monotherapies.

In combination therapy, there was a documented decrease in NPRS of 85.7%, whereas in monotherapy, the proportion was 84.6%. In addition, combination treatment had a higher proportion of decreased dyspepsia

(46.4%) than monotherapy (38.4%). There is not a significant difference between the combination and monotherapies in terms of NPRS or dyspepsia ($p>0.05$).

When gender is taken into account, out of the 54 SIEG patients, 22 are female and 32 are male, indicating that SIEG was more common in men.

9 out of the 54 participants in the trial experienced moderate side effects with brief durations, such as constipation, diarrhea, dry mouth, and restlessness, based on the toxicity profile in both combination and monotherapy.

CONCLUSION

Our current investigation compared the clinical benefits of rabeprazole as monotherapy and flupentixol/melitracen + rabeprazole, with an emphasis on patient satisfaction, mental health impacts, and the reduction of clinical symptoms associated with stress-induced erosive gastropathy. This study demonstrates that there was a reduction in stress as measured by the patients' DASS21. According to our research, combination therapy was less safe and more successful in treating patients with stress-induced erosive gastropathy; moreover, combination therapy's safety profile improved with longer treatment durations, where monotherapy was less successful yet still safe.

In summary, the combination of rabeprazole and flupentixol/melitracen is more successful in treating SIEG than rabeprazole monotherapy, even if it is still a safe alternative. To improve patient outcomes, clinicians should take into account this combination therapy, especially when stress and psychological variables are major contributors to the illness process. The best care of stress-induced erosive gastropathy requires a comprehensive treatment plan that incorporates both pharmaceutical and psychosocial therapies, as this study emphasizes.

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