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Effectiveness of Omeprazole Compared to Placebo for Recurrent Abdominal Pain in Adolescents: A Randomized Controlled Clinical Trial

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Abstract

Recurrent abdominal pain (RAP) is a common somatic complaint in adolescents, contributing to significant morbidity, impaired quality of life, and frequent school absenteeism. Although often functional in origin, proton pump inhibitors (PPIs), particularly omeprazole, are frequently prescribed under the assumption of acid-related pathology. However, clinical evidence supporting this practice in adolescents remains limited. This study aimed to evaluate the efficacy of omeprazole compared with placebo in reducing pain frequency, duration, and intensity in adolescents with RAP. A prospective, randomized, single-blind, placebo-controlled trial was conducted from August to November 2009 involving 123 adolescents aged 11–14 years who met Apley's criteria for RAP. Participants were recruited from six junior high schools and randomized into two groups: omeprazole 20 mg once daily (n=59) or placebo (n=64), administered for 14 days. Primary outcomes included pain frequency (episodes/month), pain duration (minutes/episode), and intensity (Wong-Baker FACES Pain Scale). Assessments were performed at baseline and monthly for three months post-intervention. Results showed no significant differences between groups in pain duration or intensity ($p > 0.05$). Although a significant reduction in pain frequency was initially observed with omeprazole, further analysis revealed baseline imbalances, preventing attribution of this effect to the drug. Both groups demonstrated clinical improvement, reflecting a strong placebo response. In conclusion, omeprazole 20 mg daily for 14 days did not demonstrate superiority over placebo in reducing RAP frequency, duration, or intensity. These findings do not support routine empirical use of omeprazole for undifferentiated functional RAP in adolescents.

Introduction

Recurrent abdominal pain (SPB) is one of the most commonly reported psychosomatic health problems in school-aged children and adolescents, with global prevalence estimates varying from 10% to 20% (Apley & Naish, 1958; Weydert et al., 2003). This condition, classically defined by the Apley criteria as three or more episodes of abdominal pain within a three-month period that are severe enough to interfere with daily activities, is a significant source of anxiety not only for patients, but also for parents and educators (C. Boey et al., 2000; Koh, 2011). The cumulative impact of SPB goes beyond the physical sensation of pain; it significantly erodes adolescents' quality of life (American Academy of Pediatrics Subcommittee on Chronic Abdominal Pain; North American Society for Pediatric Gastroenterology Hepatology, 2005;

Saps et al., 2009). Frequently reported consequences include disrupted sleep patterns, reduced academic performance due to difficulty concentrating, and increased school absenteeism, which in turn can limit the social participation and potential development of adolescents (Devanarayana et al., 2007; Ramchandani et al., 2007; See et al., 2001).

Etiologically, the majority of SPB cases (approximately 80-90%) are classified as functional disorders, meaning that there are no organic, anatomical or biochemical abnormalities that can explain the symptoms (Kabeer, 2017; Vanderhoff & Tahboub, 2002). The pathophysiology of functional SPB is believed to be multifactorial, involving a complex interplay between visceral hypersensitivity (increased pain perception from internal organs), gut dysmotility, and disruption of the brain-gut axis (a bidirectional communication pathway between the central nervous system and enteric nervous system). (C. Boey & Yap, 1999; Israel & Hassall, 1998; Sastroasmoro & Ismael, 2008). Nonetheless, in daily clinical practice, there is often a tendency to prescribe gastric acid-suppressing drugs, such as H2 receptor blockers or, more potently, proton pump inhibitors (PPIs) (Huang et al., 2000; Plunkett & Beattie, 2005; von Baeyer & Walker, 1999).

The use of this therapy is often based on the assumption that patient-reported symptoms-although non-specific-may overlap with those of functional dyspepsia or atypical gastroesophageal reflux disease (GERD). Omeprazole, as one of the most recognized, potent, and accessible PPIs, works by irreversibly inhibiting the H+/K+-ATPase enzyme in gastric parietal cells, thereby effectively suppressing gastric acid production (Ball et al., 2003; Chitkara et al., 2005). At the time this study was designed (around in 2009), the scientific evidence base for the effectiveness of PPIs in the management of SPB in the adolescent population was limited and ambiguous (Anbar, 2001). Their use was mostly driven by extrapolation of data from adult populations or based on empirical experience of clinicians (Sachs et al., 2006; Tolia & Boyer, 2008; Walker, 2004). The absence of solid randomized controlled clinical trials in the adolescent population creates a fundamental unanswered clinical question: does omeprazole (Janicke, 1999; Masters, 2006; Noe & Li, 2009), with its specific mechanism of action, really provide better clinical benefits than non-specific interventions such as placebo effect in managing heterogeneous recurrent episodes of abdominal pain in adolescents? Therefore, this study was specifically designed to fill such evidence gaps (Anbar, 2001; Crushell et al., 2003; Zeiter & Hyams, 2001).

Methods

This study adopted a prospective, randomized, single-blind, placebo-controlled trial design, which is recognized as the gold standard for evaluating the efficacy of pharmacological interventions. The study was conducted from August to November 2009. The study sites were purposively selected at several junior high schools in Secanggang Sub-district, Langkat Regency, North Sumatra, to reach a representative adolescent population from a semi-urban environment. All research protocols were reviewed and ethically approved by the Health Research Ethics Committee, Faculty of Medicine, University of North Sumatra, with reference number recorded (Sastroasmoro & Ismael, 2008).

The target population for this study was all secondary school students between the ages of 11 and 14 years. An initial screening process was conducted to identify subjects who met the inclusion criteria, i.e. (1) met the classic definition of SPB according to Apley's criteria (experiencing at least three episodes of abdominal pain in the past three-month period that are severe enough to interfere with normal activities), and (2) parents or legal guardians had provided written informed consent after a full explanation of the study objectives and procedures. In contrast, exclusion criteria were strictly set to ensure subject safety and sample homogeneity, including the presence of red flags indicating possible organic pathology (Boyer et al., 2006). These red flags included a history of unexplained weight loss, recurrent fever,

chronic diarrhea, bilious vomiting, gastrointestinal bleeding, as well as abnormal findings on physical examination such as organomegaly, palpable mass, or signs of anemia on initial laboratory examination (Spray, 2004; Touran et al., 2007).

A total of 123 participants who passed the screening and met all criteria were then simply randomized using the closed draw method to be allocated to one of the two treatment groups (Humphreys & Gevirtz, 2000; Suraatmaja, 2005). The intervention group (n=59) received 20 mg omeprazole capsules, while the control group (n=64) received placebo capsules containing lactose, which were made identical in terms of color, shape, and size to maintain patient blinding. The intervention was administered once daily every morning and lasted for 14 days. Primary outcome data was collected through structured questionnaires and pain diaries completed by the participants. Parameters measured were pain frequency (total number of episodes per month), pain duration (mean time in minutes per episode), and pain intensity level (assessed using the Wong-Baker FACES Pain Rating Scale). Data evaluation was conducted at four time points: at the beginning of the study (baseline) before the intervention, and at the end of the first, second, and third months after the intervention was completed to assess short-term effects and sustainability. Statistical analysis was conducted using SPSS software. The independent t-test was used to compare numerical data (frequency and duration), and the chi-square test was used to compare categorical data (pain levels). The statistical significance level was set at $p < 0.05$

Result and Discussion

The initial screening process involved 757 adolescents from six schools. Of these, 123 (16.2%) were identified as meeting the Apley criteria for SPB and were eligible to participate (Lake, 1999; Murphy, 1993). All 123 adolescents were then randomized into the two intervention groups and completed the study period. Demographic and clinical characteristics at the start of the study (baseline) showed that the two groups were relatively comparable. The mean age of the participants was approximately 13 years, with gender distribution, mean weight, height, and baseline hemoglobin levels showing no statistically significant differences between groups, indicating that the randomization process was successful in creating balanced groups (Kaminsky et al., 2006; White & Farrell, 2006).

Table 1. Characteristics of Research Respondents

Characteristics	Omeprazole (n=59)	Placebo (n=64)
Gender		
Male, n (%)	36 (61.01)	26 (40.63)
Female, n (%)	23 (38.98)	38 (59.37)
Age (years), mean (SD)	13.2 (0.83)	13.8 (1.58)
Body weight (kg), mean (SD)	38.7 (8.09)	39.7 (7.86)
Height (cm), mean (SD)	147.9 (7.57)	146.4 (8.00)
BMI, mean (SD)	17.6 (2.98)	18.4 (2.61)
Parental Income		
< Rp 500,000, n (%)	16 (27.12)	10 (15.63)
Rp 500,000 – 1,000,000, n (%)	37 (62.71)	44 (68.75)
> Rp 1,000,000, n (%)	6 (10.17)	10 (15.62)
Parental Education		
Elementary school, n (%)	3 (5.08)	3 (4.69)
Junior high school, n (%)	6 (10.17)	11 (17.19)
Senior high school, n (%)	34 (57.63)	41 (64.06)
College, n (%)	16 (27.12)	9 (14.06)
Age at menarche (years), mean (SD)	12.8 (0.88)	12.6 (0.76)

Source: Times New Roman 11, 2020

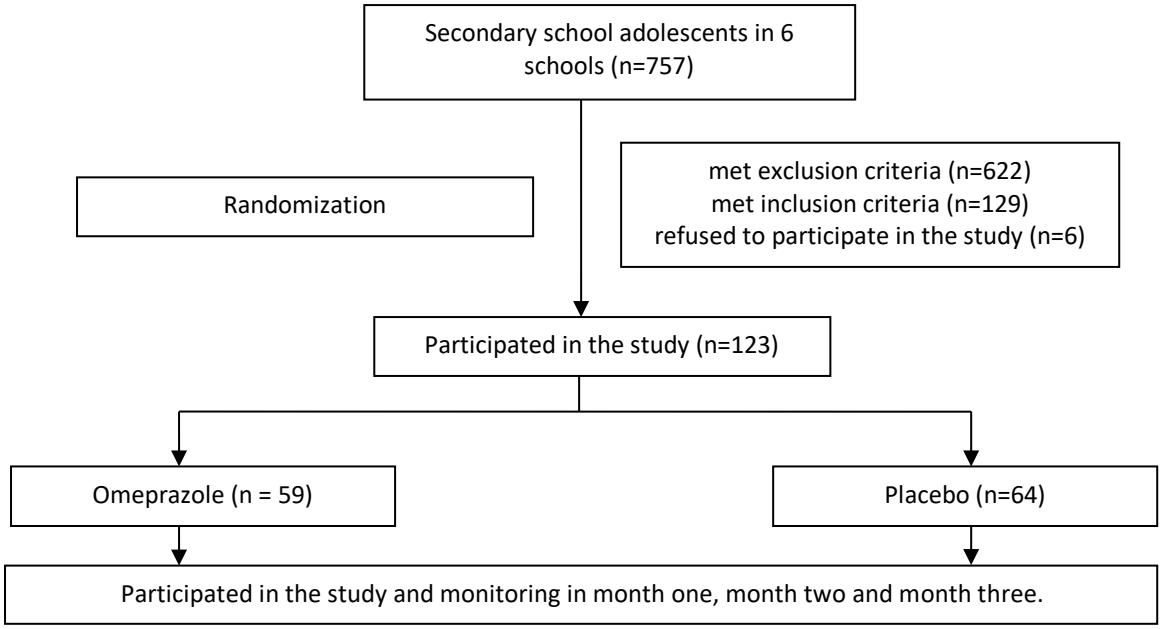

Figure 1. Research Profile

Table 2. Difference in Pain Duration Before and After Treatment

Variable	Omeprazole (n=59)	Placebo (n=64)	*P* value
Duration of pain before treatment (minutes), mean (SD)	7.71 (3.124)	6.80 (3.377)	.122
Duration of illness after 1 month treatment (minutes), mean (SD)	8.02 (3.098)	6.95 (3.406)	.075
Duration of illness after 2 months treatment (minutes), mean (SD)	7.46 (3.266)	7.03 (3.418)	.482
Duration of pain after 3 months treatment (minutes), mean (SD)	7.20 (2.976)	6.88 (3.273)	.563

Table 3. Differences in Pain Levels Before and After Treatment

Intervention	Variable	Omeprazole (n = 59)	Placebo (n = 64)	P value
Before	Mild pain level, n(%)	43 (72.88)	50 (78.12)	.775
Intervention	Moderate pain level, n(%)	12 (20.34)	11 (17.19)	
	Severe pain level, n(%)	4 (6.78)	3 (4.69)	
1 month after	Mild pain level, n(%)	38 (64.40)	48 (75.00)	.316
Intervention	Moderate pain level, n(%)	18 (30.51)	12 (18.75)	
	Severe pain level, n(%)	3 (5.09)	4 (6.25)	
2 months after	Mild pain level, n(%)	41 (69.49)	45 (70.31)	.913
Intervention	Moderate pain level, n(%)	16 (27.12)	16 (25.00)	
	Severe pain level, n(%)	2 (3.39)	3 (4.69)	
3 months after	Mild pain level, n(%)	36 (61.02)	45 (70.31)	.554
intervention	Moderate pain level, n(%)	18 (30.51)	15 (23.44)	
	Severe pain level, n(%)	5 (8.47)	4 (6.25)	

Analysis of the primary outcomes after the intervention period and three months follow-up showed consistent results (C. Boey, 2001; C. C. M. Boey & Goh, 2001). For the parameters of pain duration and pain intensity level, there were no statistically significant differences between

the omeprazole group and the placebo group at all evaluation points (first, second and third months; all $p > 0.05$). The mean duration of pain per episode in the omeprazole group was not significantly shorter than that in the placebo group. Similarly, the distribution of participants by pain level category (mild, moderate, severe) did not show a better pattern of improvement in the group receiving active therapy. This means that omeprazole did not show superiority in reducing the length and severity of pain experienced by adolescents.

Table 4. Differences in Pain Frequency Before and After Treatment

Variable	Omeprazole (n = 59)	Placebo (n = 64)	P value
Frequency of pain before treatment (times), mean (*SD*)	7.02 (2.720)	5.52 (2.576)	.002
Frequency of illness after 1 month treatment (times), mean (*SD*)	7.44 (3.013)	5.48 (2.539)	.0001
Frequency of illness after 2 months treatment (times), mean (*SD*)	7.15 (2.846)	5.41 (2.435)	.0001
Frequency of illness after 3 months treatment (times), mean (*SD*)	6.68 (2.855)	5.66 (2.727)	.045

Regarding the outcome of pain frequency, the analysis showed statistically significant differences between the two groups at each monthly evaluation (all $p < 0.05$). However, interpretation of these findings should be done with caution (Thiessen, 2002). It should be noted that at baseline measurement, the group randomized to receive omeprazole happened to have a higher mean baseline pain frequency compared to the placebo group. When further analyzed in the context of the other two outcomes (duration and intensity) showing no improvement, this statistical difference in frequency most likely does not reflect the true clinical effectiveness of omeprazole. Instead, both groups showed a downward trend in pain frequency over time, indicating the influence of other factors, such as the natural course of the disease or a strong placebo effect, which is common in studies of functional pain conditions.

Discussion

The main findings of this study unequivocally show that administration of omeprazole at a dose of 20 mg for two weeks is not superior to placebo in the management of recurrent abdominal pain in the adolescent population studied. This result has important clinical implications, highlighting the possibility that the underlying pathophysiology of SPB in the majority of adolescents in this population is not primarily mediated by excess gastric acid secretion. This finding is very much in line with the modern understanding of *functional abdominal pain disorders* (FAPD), which emphasizes the central role of non-acid mechanisms such as visceral hypersensitivity (lower pain thresholds in internal organs), gastrointestinal dysmotility, and complex dysregulation of the *brain-gut axis*. In other words, the source of the problem is likely not the "acidity" of the stomach, but rather how the nervous system processes signals from the gut (Croffie et al., 2000; Di Lorenzo et al., 2001).

The failure of omeprazole to show significant benefit is likely also reinforced by the methodological design of this study. The use of the Apley criteria, although standard for its time, was broad and unable to distinguish subtypes of SPB. These criteria combine a variety of conditions under one diagnostic umbrella, without specifically screening out the subgroup of patients whose symptoms may be dominated by dyspeptic syndrome (epigastric pain, feeling full after eating), where acid-suppressing therapy theoretically has a greater chance of success. This is in contrast to several other studies that found benefit from H2-receptor antagonists (such as famotidine), which often recruited patients with more obvious dyspeptic symptoms. Therefore, the population in this study was more heterogeneous, which may have "diluted" the

potential positive effect of omeprazole in the small subgroup that may be responsive (C. Boey, 2001).

Study Limitations

It is important to acknowledge several limitations inherent to this study. Firstly, the use of the Apley criteria, as discussed, is now considered less specific than the more recent ROME diagnostic criteria (e.g., ROME IV), which classify FAPD into more clearly defined subtypes. Secondly, the nature of outcome data (frequency, duration, intensity of pain) is highly subjective, relying entirely on the perception and self-reporting of adolescent participants, which can be influenced by various psychological and social factors. Thirdly, despite clear instructions to participants, monitoring medication adherence in community-based studies such as this is always a challenge, so potential bias due to non-adherence cannot be completely ruled out.

Clinical Implications and Research Directions

Although the data of this study was collected more than a decade ago, the results remain highly relevant and serve as a strong evidence-based reminder of the practice of routinely prescribing PPIs for all cases of SPB in adolescents. The findings strongly support a more thoughtful and *patient-centered* clinical approach. This approach prioritizes in-depth history taking and careful physical examination to rule out *red flags* and understand the patient's biopsychosocial context, before rushing to initiate empirical pharmacological therapy. For future studies, it is highly recommended to use the ROME IV (or later) diagnostic criteria to recruit a more homogeneous and well-defined patient cohort. This will allow evaluation of the effectiveness of targeted therapies in specific subtypes of FAPD, such as functional dyspepsia *syndrome* versus *irritable bowel* syndrome, where the response to different therapies may vary considerably.

Conclusion

Based on the evidence generated from this randomized controlled clinical trial, administration of a standard dose of omeprazole for 14 days was not shown to be more effective compared to placebo administration in terms of reducing the frequency, duration and intensity of recurrent episodes of abdominal pain in a general population of adolescents. These findings provide a strong evidence base that does not support the use of omeprazole as a first-line pharmacological therapy for the adolescent population with functional undifferentiated SPB complaints. Clinical practice should focus more on a holistic approach that includes education, reassurance, and biopsychosocial interventions, with pharmacotherapy reserved for selected cases after careful evaluation.

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