

# The Effect of Pinaverium Bromide (Dicetel) in Irritable Bowel Syndrome

İRRİTABL BARSAK SENDROMUNDA DİCETAL

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## SUMMARY

The effect of pinaverium bromide (Dicetel), an anti-spasmodic agent acting on the gastrointestinal system as investigated in 110 patient with irritable bowel syndrome in a placebo controlled study. Hundred patients were treated with pinaverium bromide (3x50 mg/day) tablets and ten patients with placebo for two weeks. We observed that pinaverium bromide was significantly effective than placebo in irritable bowel syndrome ( $p<0.01$ ). It was not effective in the patients who had additional organic gastrointestinal disease. A few adverse reactions were seen in the patients who used pinaverium bromide. We conclude that pinaverium bromide is a safely and effective drug in the treatment of irritable bowel syndrome.

## ÖZET

Bu çalışmada, gastrointestinal sistemde antispasmodik özellik gösteren Pinaverium bromide'in irritable barsak sendromlu hastalardaki etkisi araştırıldı. Irritabl barsak sendromu tanısı konan 110 hastadan, 100'üne, günde 3x50 mg Pinaverium bromide oral yolla, iki hafta süreyle, 10'una da aynı süreyle plasebo tabletleri verildi. Çalışmanın sonunda irritable barsak sendromlu hastalarda, Pinaverium bromide'in anlamlı bir şekilde ( $p<0.01$ ) etkili olduğu bulundu. Tedaviden yarar görmeyen hastalarda irritable barsak sendromuna ilaveten bazı organik gastrointestinal sistem bozukluklarının mevcut olduğu görüldü. Ayrıca ilacın sistemik yan etkilerinin çok az olduğu tesbit edildi. Pinaverium bromide'in irritable barsak sendromlu hastaların tedavisinde güvenle kullanılabilecek bir ilaç olduğu kanaatine varıldı.

Key Words: Irritable bowel syndrome, Pinaverium bromide

Anahtar Kelimeler: Irritabl barsak sendromu, Pinaverium bromide

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Irritable bowel syndrome (IBS) is a motor disorder consisting of altered bowel habits, abdominal pain, and the absence of detectable organic pathology. Symptoms are markedly influenced by psychological factors and stressful life situations (1).

The incidence of IBS has been shown between 15 to 20% in different studies (2,3). Although in some patients symptoms are very slight, in western countries 20-50% of patients can be diagnosed IBS who refers to gastroenterology clinics (4,5).

Organic disorders should be excluded when IBS diagnosed because there are similarities between IBS and organic disorders of gastrointestinal system. Therefore, diagnosis of IBS is very costly for patients and for social warfare organizations.

Manning et al (6) confirmed that decrease in the abdominal pain after bowel movement, increases in the bowel movement with abdominal pain and findings as distention is more frequent in IBS more than they are in organic disorders. Abdominal pain, flatulence, diarrhea-constipation, presence of mucus in stool has been shown more significantly in IBS by Kruis et al (7).

Pathogenesis of IBS is not clarified yet, but there are gastrointestinal motility abnormalities in IBS. Symptoms of IBS appear after or during period of stress and emotional tension (1,8). Motility abnormalities have been shown in colon and also in small intestine (9).

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Close physician-patient relationship is very important for improvement of emotional situation in the treatment of IBS. Medical therapy is necessary to reduce abdominal pain and distention, especially during the symptomatic periods. Pinaverium bromide (PB) is a calcium channel blocker that affects locally and minimally absorbed in the gastrointestinal tract. It selectively shows antispasmodic effect on intestinal smooth muscle, therefore, it has been used in the treatment of IBS (10).

In this study we investigated the effect of PB in IBS patients in a placebo controlled study.

**MATERIALS AND METHODS**

In this study 110 IBS patients were evaluated. Hundred patients were treated with PB and 10 patients with placebo as a control group.

In the treatment group 70 patients were female and 30 patients were male (F/M:7/3) and mean ages were 42 in females and 33 in males. In placebo group, there were 7 females and 3 males, and mean ages were 39 and 40 in female and male patients, respectively.

In both groups, dyspepsia, pain, gas, constipation, diarrhea and nausea were asked and answers were recorded. All patients were evaluated by endoscopic and radiological examinations. Accompanying disorders were also recorded.

Patients were treated with PB (3x50 mg/day) or placebo (3x1/day) for two weeks. Responses to therapy were evaluated as "very well", "well", "mild" and "no response". Results were statistically compared with chi-square test.

**RESULTS**

In treatment group 10 patients were excluded from the study. 4 patients due to self discontinuation of therapy and 6 patients due to adverse effects. In this group 30 patients responded very well, 24 patients well, 21 mildly and 15 patients did not respond. In control group 2 patients re-

sponded very well and 1 patient mildly. Seven patients had no difference in their symptoms after treatment (Table 1).

The improvement rates were 75% in treatment and 30% in the control group. The difference between groups was statistically significant (p<0.01) (Table 2). In treatment group 15 cases did not respond. Eleven of these 15 patients showed additional gastrointestinal disease (Table 3).

Adverse effects in 6 patients were skin rash in 3, dizziness in 2 and pruritis in 1.

**DISCUSSION**

Irritable bowel syndrome is a functional disease of intestine and seen very frequently in all populations. The main cause of the disease is not well known but alterations in small and large intestinal motility that can be affected by psychological factors are very important (9). Psychotherapy and hypnotherapy need long time for this chronic disease. Medical therapy is necessary for the urgent symptoms as abdominal distention, pain and altered bowel habit. Drugs having antispasmodic or anticholinergic effects are being commonly used in the treatment of IBS (11). PB is an antispasmodic drug absorbed minimally from gut. Passaretti et al (9) had shown a decrease with local effect of rectal PB in the colon motility stimulated by neostigmine. This study also confirms PB's local action when given by oral route. Bouchoucha et al (12) have shown that PB decreases the frequency of jejunal contractions in IBS patients. Awad et al (13) found that PB is effective by decreasing the electrical and mechanical responses of gastrointestinal tract in IBS patients. In a multicenter clinical trial, PB treatment had shown clinical improvement in 90%, tolerated by 96.3% and side effect in 3.7% of IBS patients (14).

In our clinical trial, clinical improvement was 75%. Eleven patients did not respond because of additional gastrointestinal diseases. These results were similar to the results of the multi-centered studies in the literature. Also, we couldn't assess any side effect as those

Table 1. Treatment results in both groups

	Respond Very well	Well	Mild	No Respond	Adverse Effect	Discontf
PB* n:100	30	24	21	15	6	4
Placebo n:10	2	-	1	7	-	-

\*Pinaverium bromide, f discontinuation of therapy.

Table 2. Overall improvement in both groups

Pinaverium bromide n:100	75%
Placebo n:10	30%

Table 3. Associated diseases in non responders

IBS+Duodenal ulcer	7%
IBS+Cholecystopathy	2%
IBS+Psychologic disorders	2%

seen with anticholinergic drugs in our IBS patients. This can be explained by minimal absorption of PB from gastrointestinal tract.

As a result, PB can be used in IBS safely and effectively, since it is a drug that has minimal absorption from gastrointestinal tract and has regulatory effects on the motility of small and large intestine by local action.

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