Clinical Evaluation of the Efficacy and Safety of SJ-200 in the Management of Spasmodic Visceral Pain

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ABSTRACT
An open clinical trial was conducted with the herbal formulation, SJ-200, to treat spasmodic visceral pain. Twenty eight patients suffering with spasmodic abdominal pain were selected and given SJ-200 at a dose of 2 capsules, followed by 1 capsule after an hour and another after 8 hours, followed by 1 capsule, thrice daily, for the next 3 days. Of the 28 patients subjected to the clinical trial, pain was relieved immediately in 4 patients, 13 patients had delayed relief and results were ambiguous in 11 patients, which indicates that the SJ-200 is effective in spasmodic visceral pain.

INTRODUCTION
Abdominal pain is one of the commonest complaints in medical outpatient departments. The causes of abdominal pain are very broad and include gastritis, functional dyspepsia, intestinal colic in intestinal infestations, acute gastroenteritis, renal colic, dysmenorrhea and irritable bowel syndrome (IBS).

Gastritis pain in the epigastrium is associated with nausea and sometimes vomiting. It is caused by stress, drugs like nonsteroidal inflammatory drugs NSAIDs and alcohol. It is also caused by Helicobacter pylori. The symptoms of functional dyspepsia are similar to gastritis but also include other symptoms like early satiety, abdominal distension and fullness after food.

Recurrent colicky pain is caused by cholecystolithiasis or renal colic. In cholecystolithiasis, the pain, localised to the right upper quadrant and often radiating to the right lower scapula, is associated with nausea and vomiting, whereas in renal colic, the pain is very severe, usually starts at the loin and later shifts to the lumbar region.

Pain in the abdomen may be associated with loose stools in conditions like acute gastroenteritis, IBS, carbohydrate intolerance, inflammatory bowel disorders like Crohn’s disease and ulcerative colitis, etc. In IBS, eating commonly triggers symptoms such as bloating, flatulence, nausea, dyspepsia and pyrosis. Pain is present over one area of the colon, associated with a period of constipation alternating with a more normal stool frequency, relieved by passing of stools. Many a time there is a sensation of incomplete evacuation even
after defecation. In carbohydrate intolerance, pain in the abdomen (cramps) usually follows ingestion of foods rich in carbohydrates. Pain abdomen is associated with borborygmi, bloating, flatus, nausea and diarrhea.

Along with abdominal pain and diarrhea, Crohn’s disease and ulcerative colitis are associated with bloody stools. The latter may be present with life threatening complications like severe hemorrhage, toxic mega colon and intestinal perforation.

The causes of abdominal pain may be very trivial and require symptomatic treatment. Though a probable diagnosis can be arrived at almost immediately, to arrive at the correct diagnosis requires time, requiring interim treatment to subside the pain till the definitive treatment is started, which may be continued along with the definitive treatment. The Himalaya Drug Company, Bangalore, has a new formulation Himcospaz (SJ-200), which is effective as well as safe. The current clinical trial was conducted to assess the efficacy and safety of the drug, Himcospaz (SJ-200).

MATERIAL AND METHODS
Twenty eight patients complaining of spasmodic abdominal pain of varied aetiology attending the Department of Kayachikitsa, S.S. Hospital, Banaras Hindu University, Varanasi, were recruited for the trial. The patients were thoroughly examined and the salient clinical features were recorded through a clinical scoring.

Of the patients selected, 20 of them were male and 8 were female, between 11-80 years. Fifteen of them had acid peptic disorders, 7 had IBS, 2 had chronic amoebiasis and worm infestations, 2 had Koch’s abdomen, and 1 each had ulcerative colitis and cholelithiasis.

The pain was dull and aching in 23 patients, and spasmodic in 5 patients. Ten patients had mild, 16 patients had moderate and 2 had severe degree of pain.

Sixteen patients had intermittent pain and 12 patients had pain for a long duration. Among the patients with pain abdomen, 3 had vomiting and 2 patients had dysuria.

The patients were administered 2 capsules, followed by another capsule after 1 hour, and 1 more capsule after 8 hours, and followed by 1 capsule thrice daily for the next three days. The response to treatment was recorded by symptomatic evaluation in the following terms:
1. Relief from pain - Immediate / Delayed
2. Recurrence of pain after first relief – Yes / No
3. Pain remission for more than a week – Yes / No
4. Diarrhoeal frequency – Reduced / Unchanged
5. Other observations.
RESULTS
Twenty eight patients with abdominal pain were recruited for the evaluation of efficacy and safety of SJ-200. The pain was dull in 23 patients and spasmodic in 5 patients.

After treatment with SJ-200, 4 patients had immediate relief from pain (14.29%) and 13 patients (46.43%) had relief from pain after 2 hours. Only 11 patients (39.28%) could not commit regarding the pain (Table 1). There was recurrence of pain in 9 (32.15%) in 28 patients, i.e. 8 (28.57%) patients had no recurrence of pain. The recurrence was observed in patients with relief. Eleven patients (39.28%) were unable to express whether the pain recurred or not (Table 2). There was pain remission in 5 cases (17.86%), and there was no remission of pain in 12 patients (42.86%). Eleven patients (39.28%) were not clear regarding the recurrence of the pain (Table 3).

This clinical trial involving 28 patients with chronic recurrent abdominal pain indicated that SJ-200 relieved mild to moderate colic, and abdominal pain of various aetiologies. This can be further confirmed by involving larger populations of patients.

DISCUSSION AND CONCLUSIONS
The observations reveal that a majority of the patients were young adult males. The diagnoses in these patients were non-ulcer dyspepsia, irritable bowel syndrome, chronic amoebiasis, ulcerative colitis, Koch’s abdomen and chronic chololithiasis. Most patients had mild to moderate degrees of pain, and the nature of pain was dull aching. The duration of pain varied from few minutes to continuous.

The observations suggested that SJ-200 had a significant effect in relieving mild to moderate abdominal pain.

SJ-200 has antispasmodic herbs like *Apium graveolens*, *Foeniculum vulgare* and *Zingiber officinale*. Apigenin, an active constituent of *Apium graveolens*, was reported to inhibit norepinephrine-induced contractions in rabbit’s aortic preparations in a dose-dependant manner. The essential oils of *Foeniculum vulgare* exhibited antispasmodic effect in the rat’s uterus preparations. *Zingiber officinale* was proven effective in inhibiting the intestinal, gastric and colonic motility. The spasmolytic activity of *Zingiber officinale* could be also

| Table 1: Pattern of relief in pain in 28 cases of abdominal pain following trial treatment |
|---------------------------------|-----------------|------------------|
| No. of cases | Percentage |
| Immediate | 04 | 14.29 |
| Delayed | 13 | 46.43 |
| Ambiguous | 11 | 39.28 |
| Total | 28 | 100% |

| Table 2: Recurrence of pain after first two days during trial treatment |
|---------------------------------|-----------------|------------------|
| Pain recurrence | No. of cases | Percentage |
| Yes | 09 | 32.15 |
| No | 08 | 28.57 |
| Ambiguous | 11 | 39.28 |
| Total | 28 | 100% |

| Table 3: Pain remission after 3 days of treatment |
|---------------------------------|-----------------|------------------|
| Pain remission | No. of cases | Percentage |
| Yes | 05 | 17.86 |
| No | 12 | 42.86 |
| Ambiguous | 11 | 39.28 |
| Total | 28 | 100% |
attributed to gingerol, an active constituent that was found to inhibit prostaglandin, biosynthesis and serotonergic activity\textsuperscript{11}.

The combination of these active constituents could be responsible for the synergistic antispasmodic effect. SJ-200 in experimental models is known to suppress 5-HT induced intestinal contractions. Thus, it could be useful in IBS, where 5-HT levels are known to be increased following food intake.

Patients with IBS have several episodes of remissions and exacerbation of acute symptoms. During the stage of acute exacerbation of chronic IBS, SJ-200 may be administered for prolonged use, which may range from 4 to 6 weeks. Although in this clinical trial SJ-200 was used for 3 days to determine mainly the relief of pain, in patients with severe abdominal colicky pain, SJ-200 may be administered as 2 capsules twice daily. This may be continued depending upon the type and severity of the abdominal pain.

In view of safety, easy availability and cost effectivity, SJ-200 was proven useful in routine treatment of patients with spasmodic visceral pain of non-specific nature.

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**REFERENCES**


