19. Post-anesthesia and Postoperative Pain

Reference

Miyazaki M, Yasui M, Ikenaga M, et al. The effect of Shakuyaku-kanzo-to (Tsumura TJ-68) on pain after hemorrhoidectomy – a prospective randomized study –. *Journal of the Japan Society of Coloproctology* 2012; 65: 313–7 (in Japanese with English abstract).

1. Objectives

To evaluate the effectiveness of shakuyakukanzoto (芍薬甘草湯) for pain after hemorrhoidectomy

2. Design

Randomized controlled trial (RCT).

3. Setting

Not mentioned (the first author belonged to the Department of Coloproctology, Dojinkai Dojin Hospital & the Department of Surgery, Osaka National Hospital), Japan.

4. Participants

Thirty-nine patients with hemorrhoids or mucosal prolapse who had undergone semi-closed hemorrhoidectomy.

5. Intervention

Arm 1: after hemorrhoidectomy, diclofenac sodium 25 mg t.i.d. plus TSUMURA Shakuyakukanzoto (芍薬甘草湯) Extract Granules 2.5 mg t.i.d. taken orally (n=18).

Arm 2: after hemorrhoidectomy, diclofenac sodium 25 mg t.i.d. alone taken orally (n=21).

In cases of poor analgesic action, both groups were permitted intramuscular injection of the painkillers pentazocine 15 mg plus hydroxyzine pamoate 25 mg, diclofenac sodium 50 mg suppository, or single-use loxoprofen sodium orally.

6. Main outcome measures

Pain score (maximum score for the day on a 10-point visual analog scale), type of pain (when resting, when defecating, when mobile), number of days till pain score fell below three, number of days till pain disappeared when resting, waking in the night due to pain, use of painkiller injection, additional use of nonsteroidal anti-inflammatory drugs (NSAIDs) by suppository or by mouth.

7. Main results

Excluding the day of surgery, pain scores were significantly lower in arm 1 compared to arm 2 on each day from the first to the ninth day after surgery ($P<0.05$). "Type of pain" results were not reported in the original paper. Significant differences between arm 1 and arm 2 were noted in the mean number of days till the pain score fell below three (2.1 vs 5.2; $P<0.05$) and use of painkiller injections (three times [17%] vs ten times [48%]; $P<0.05$) but not in the number of days till pain disappeared when resting, additional use of non-steroidal anti-inflammatory drugs (NSAIDs), or waking in the night due to pain.

8. Conclusions

Administration of shakuyakukanzoto in addition to NSAIDs is effective in improving pain after hemorrhoidectomy.

9. From Kampo medicine perspective

Not mentioned.

10. Safety assessment in the article

No adverse effects of shakuyakukanzoto were observed.

11. Abstractor's comments

This clinical study investigated the effectiveness of shakuyakukanzoto in addition to NSAIDs for pain after hemorrhoidectomy. While hemorrhoidectomy is excellent therapy, it is avoided because of the postoperative pain. This very interesting clinical study is intended to investigate whether that complication can be alleviated based on the unique idea of physicians. On the other hand, the pain score graphs imply that pain began to decrease in the shakuyakukanzoto group the day after surgery, even though there was no significant difference, which suggests a problem with the participant allocation method. Furthermore, while the mean pain scores were not significantly different immediately after surgery (5.7 without shakuyakukanzoto and 5.1 with shakuyakukanzoto), the difference was significant on the eighth day (2.4 and 2.1, respectively). It is also possible that variation had decreased by the eighth day; the mention of not just mean values but standard deviation suggests the possibility of deliberate emphasis on statistical differences. However, as the authors mention in the discussion, their treatment methods were relatively simple and potentially could alleviate pain, and should be further evaluated in a large-scale multi-center study.

12. Abstractor and date

Goto H, 31 December 2013.