19. Injury, Poisoning, and Postoperative Pain

Reference

Komasawa N, Yamamoto K, Ito Y, et al. Preoperative administration of jidabokuippo, a Kampo medicine, alleviates postoperative pain after tooth extraction with mandible bone removal under general anesthesia: a prospective, single-blind, randomized controlled trial. *Journal of Alternative and Complementary Medicine* 2018; 24: 1214-8. CENTRAL ID: CN-01702650, Pubmed ID: 29993259, UMIN ID: UMIN000019038

1. Objectives

To determine the efficacy and safety of preoperative administration of jidabokuippo（冶打撲一方） in treating postoperative pain after tooth extraction with mandible bone removal under general anesthesia.

2. Design

Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).

3. Setting

One hospital (the author belongs to the Department of Anesthesiology and Oral and Maxillofacial Reconstructive Surgery, Osaka Medical College), Japan.

4. Participants

One hundred and fifty-six patients with an American Society of Anesthesiologists Physical Status class of 1 or 2 who were scheduled to undergo tooth extraction surgery under general anesthesia between February 2016 and March 2018. Patients were excluded if they were pregnant, used analgesics, anti-inflammatory drugs, or other Kampo formulations, or were scheduled to undergo only tooth extraction without mandible bone removal under general anesthesia.

5. Intervention

Arm 1: JDI group: TSUMURA Jidabokuippo（冶打撲一方）Extract Granules 7.5 g in three divided doses (at bedtime on the day before surgery, in the morning and around noon of the day of surgery) (n=30).
Arm 2: Control group: No administration of TSUMURA jidabokuippo Extract Granules (n=30).
In both Arm 1 and Arm 2, the surgery under general anesthesia was performed in the afternoon.

6. Main outcome measures

Primary endpoint: Severity of postoperative pain (measured using a numeric rating scale [NRS])
Secondary endpoints: Severity of postoperative nausea (measured using an NRS), number of patients who requested NSAIDs, time to the first NSAID request, number of additional NSAID administrations within 24 hours after anesthesia recovery.

7. Main results

Of the 156 patients screened, 96 patients were excluded because their surgery did not include mandible bone removal. The postoperative pain NRS score at 1 hour after anesthesia recovery did not significantly differ between the two groups. At 3 and 24 hours after anesthesia recovery, the postoperative pain NRS was significantly lower in Arm 1 (P<0.001 for both 3 and 24 hours). The number of patients who requested NSAIDs within 24 hours after anesthesia recovery was significantly lower in Arm 1 (21 patients in Arm 1 and 29 patients in Arm 2; P=0.006). The number of additional NSAID administrations within 24 hours after anesthesia recovery was significantly higher in Arm 2 (1.0±0.8 times in Arm 1 and 2.7±0.8 times in Arm 2; P<0.001). The time to the first NSAID request after anesthesia recovery was significantly longer in Arm 1 (6.5±3.4 hours in Arm 1 and 3.4±2.2 hours in Arm 2; P<0.001). The severity of nausea did not significantly differ between the groups.

8. Conclusions

Jidabokuippo administration before general anesthesia effectively decreased the severity of postoperative pain after anesthesia recovery in patients who underwent tooth extraction with mandible bone removal.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

No side effects related to jidabokuippo, such as edema or hypokalemia, etc., were noted during the study.

11. Abstractor's comments

This large RCT evaluated the efficacy of preoperative administration of jidabokuippo on postoperative pain after tooth extraction with mandible bone removal under general anesthesia, and produced results that are clinically meaningful. The severity of postoperative pain was significantly lower in the jidabokuippo group at 3 and 24 hours after anesthesia recovery, though not at 1 hour after anesthesia recovery. The authors take a cautious approach to the clinical application of the treatment because this was not a placebo-controlled study. However, results of this clinical study provide adequate grounds for further clinical studies to confirm the efficacy of treatment, establish the therapeutic method, etc. Thus, future advances in the clinical research are awaited.

12. Abstractor and date

Kogure T, 11 September 2019.