The Effect of auricular acupuncture on pain during colonoscopy with midazolam and pethidine

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Abstract. Colonoscopy is the standard procedure for colorectal cancer screening. One of its common complications is abdominal pain. Analgesia has not provided favorable outcomes so various complementary practices have been developed, including auricular acupuncture. In this study, a randomized controlled trial of 56 patients who underwent colonoscopy was conducted to determine the effect of acupuncture on the pain experienced during colonoscopy. Subjects were divided into two groups: The first received acupuncture combined with midazolam and pethidine, while the second were administered placebo puncture in addition to midazolam and pethidine. The median Critical Care Pain Observation Tool (CPOT) score was lower in the auricular acupuncture group than in the placebo puncture group (0.7 [0–4.83] vs. 1.9 [0–6.20]; p = 0.010), while there were no significant differences to median Visual Analog Scale (VAS) scores (29 [0–100] vs. 44.5 [0–100]; p = 0.147), heart rate changes (−2.58 [14.31] vs. −2.43 [12.28]; p = 0.970), or the mean time to the cecum (16 [8–51] vs. 22 [5–63]; p = 0.206). Auricular acupuncture combined with midazolam and pethidine was found to be effective at reducing pain during colonoscopy.

1. Introduction
Colonoscopy is a procedure commonly performed to diagnose and treat various conditions and symptoms. It is also used as a screening tool and colorectal neoplasia survey. The use of colonoscopy as a preventive procedure for colon cancer has increased every year. In 2010, approximately 10 million patients underwent colonoscopy in the United States [1]. Data from the Cipto Mangunkusumo Hospital suggests that as many as 921 patients underwent colonoscopy in 2007–2008 [2]. Despite various developments in medical technology, colonoscopy has continued to be a very invasive procedure that causes discomfort and pain. This could lead to a lack of patient cooperativeness and reduce patient satisfaction. It could even cause patients to refuse the procedure in the future. Therefore, sedation and analgesia are commonly used during colonoscopy [3].

Sedation is used to reduce anxiety and discomfort, improve patient tolerance, increase satisfaction, reduce the risk of trauma, and produce optimal conditions for a holistic examination of the colon. The use of sedation during colonoscopy remains controversial due to questions surrounding its risks, benefits, and expense. Although it increases the number of polypectomies, the polyp detection rate, and the rate of reaching the cecum while reducing the time needed to intubate the cecum [4], it does not increase the procedure’s success rate or decrease the time needed to reach the cecum. Additionally,
sedation prolongs the length of inpatient care [5], which increases total costs [4] and the risk of complications [6]. A number of recent studies have evaluated the effectiveness of various methods to reduce sedative doses during colonoscopy. This includes intensive research on the use of carbon dioxide and warm water as substitutes for air insufflation [7].

Several studies have shown that acupuncture has analgesic effects during gastrointestinal endoscopy procedures. Lee et al. (2004) systematic study of six randomized control trials investigating the use of acupuncture during gastrointestinal endoscopy found it to have effects similar to conventional premedication but better than placebo puncture. Nevertheless, more specific research examining larger sample groups is necessary to confirm the effect of acupuncture as an additional intervention during gastrointestinal tract endoscopy [8]. Auricular acupuncture has been proven to be an effective pain management tool in patients with various conditions, including dysmenorrhea, post-operative pain, pelvic fracture, low back pain, and bone marrow aspiration. This technique is advantageous because the needle does not obstruct the procedure [9]. Based on this reason, it was decided to examine the effects of auricular acupuncture on the pain experienced by patients undergoing colonoscopy.

2. Materials and Methods

This study was conducted after receiving approval from the Medical Research Ethics Committee of the Faculty of Medicine at Universitas Indonesia and Cipto Mangunkusumo Hospital (approval number 87/UN2.F1/ETIK/2016). Permission to conduct the research was obtained. The design chosen for this study was a double-blind randomized controlled clinical trial. Randomization was completed using computer-based random allocation, and a concealment technique was used to avoid selection. In order to meet the inclusion criteria for this study, subjects had to be 18–60 years of age, willing to sign the informed consent form, and in compliance with the research protocols until its completion. Exclusion criteria included: a contraindication of acupuncture, such as pregnancy, emergency case, malignancy, or the presence of a blood-clotting disorder; high hypertension (>200 mmHg), fever (>38°), or blood sugar level (>200 mg/dl); the presence of an injury, infection, or scar at the acupuncture site; and the use propofol as analgesia during colonoscopy.

The tools and materials used in this study were a Mitutoyo SJ 301 surface roughness tester, an incubator, plastic pots, an RoHS Electric Toothbrush® soft brush (0.16 mm), AA batteries, plastic filling, a light-curing unit (LEDMAX-Hilux) with 700 mW/cm² irradiance, cylinder molds 4 mm in diameter and 2 mm tall, glass slides, a ruler, a mixing slab, an ultrasonic cleanser, aquadest, herbal toothpaste HPAI, Ciptadent® toothpaste, composite resin veneer (3M ESPE shade A2 nanofilled light-cured composite resin, batch no. N662388), silicon oil, and Mylar strips.

Patients were placed in either a lying or sitting position, and aseptic and antiseptic were applied to the acupuncture site. Manual acupuncture was then performed on the ear by inserting press needles into the skin at the MA-TF 1 Shenmen, MA-IC 1 lung, MA-CW 2 thalamus, and MA-SC 4 colon points using tweezers 30 min prior to colonoscopy. The press needles were then covered with plaster for the duration of the procedure. The stimulation was by giving pressure for 1 min on each point immediately after the needle was inserted. The needles were removed after the procedure. Meanwhile, plaster that (not containing acupuncture needles) was administered to the placebo puncture group at the MA-TF 1 Shenmen, MA-IC 1 lung, MA-CW 2 thalamus, MA-SC 4 colon points 30 min prior to colonoscopy and left in place until the end of the procedure. Pressure was applied on each point for 1 min immediately after the elastic bandages were attached.

Data were collected using the Visual Analog Scale (VAS) and the Critical-Care Pain Observation Tool (CPOT). Pulsation and the time needed to reach the cecum were also considered. The VAS is a tool used to assess pain intensity. It is a 100-mm line measured immediately after colonoscopy. The CPOT measures pain intensity using a questionnaire that assesses facial expression, body movement, muscle contraction, and compliance in ventilator or vocalization use. The CPOT was used to measure pain intensity at zero minute of the procedure, at 5-min intervals throughout colonoscopy, and immediately after its completion. Pulsation data gathered from each patient’s upper left arm was
recorded using a digital sphygmomanometer (AND Medicine) at 5-min intervals during the procedure and immediately after its completion. The time needed to reach the cecum was defined as the duration of time between the insertion of the colonoscopy into the rectum and its arrival at the proximal of the ileocecal valve (when the caput cecum, including the medial cecum wall between the ileocecal valve and appendices orificium, was seen by the operator). Pulsation was recorded by a competent, independent observer before the acupuncture therapy and after the colonoscopy; the VAS, CPOT and time needed to reach the cecum were recorded by a competent, independent observer during and after the colonoscopy. The data collected were statistically analyzed using SPSS V.20. An independent sample t-test was used to analyze numerical variables. A p-value less than α (p < 0.05) indicated a statistically significant difference between the compared variables.

3. Results and Discussion

3.1 Results
This study was conducted on 56 patients who underwent colonoscopy and fulfilled the inclusion and exclusion criteria. Each patient was randomly allocated into one of two groups: The first received auricular acupuncture and medicaments (the acupuncture group), while the other was administered placebo puncture and medicaments (the placebo puncture group). Each group consisted of 28 subjects who followed the research protocol. Five subjects (three from the acupuncture group and two from the placebo puncture group) experienced failed procedures due to colon obstruction (Table 1).

| Characteristics                  | Acupuncture Group (n = 25) | Placebo Puncture Group (n = 26) | Total (n = 51) | p-value |
|----------------------------------|-----------------------------|---------------------------------|----------------|---------|
| Age (years)                      | 52.00 (24–60)               | 50.50 (25–60)                   | 51 (24–60)     | 0.712a  |
| Gender                           |                             |                                 |                |         |
| Male, n (%)                      | 9 (36.0)                    | 9 (34.6)                        | 18 (35.3)      | 0.918b  |
| Female, n (%)                    | 16 (64.0)                   | 17 (65.4)                       | 33 (64.7)      |         |
| Formal Education                 |                             |                                 |                |         |
| No Education, n (%)              | 1 (4.0)                     | 0 (0.0)                         | 1 (2.0)        | 0.511c  |
| Junior, n (%)                    | 6 (24.0)                    | 6 (23.1)                        | 12 (23.5)      |         |
| Junior High, n (%)               | 1 (4.0)                     | 5 (19.2)                        | 6 (11.8)       |         |
| High School, n (%)               | 9 (36.0)                    | 8 (30.8)                        | 17 (33.3)      |         |
| College/University, n(%)         | 8 (32.0)                    | 7 (26.9)                        | 15 (29.4)      |         |
| Endoscopy History                |                             |                                 |                |         |
| Yes, n (%)                       | 10 (40.0)                   | 8 (30.8)                        | 18 (35.3)      | 0.490b  |
| No, n (%)                        | 15 (60.0)                   | 18 (69.2)                       | 33 (64.7)      |         |
| Chronic Pain                     |                             |                                 |                |         |
| Yes, n (%)                       | 0 (0.0)                     | 1 (3.8)                         | 1 (2.0)        | 1.000d  |
| No, n (%)                        | 25 (0.0)                    | 25 (96.2)                       | 50 (98.0)      |         |
| Operator Experience              |                             |                                 |                |         |
| Expert, n (%)                    | 4 (16.0)                    | 5 (19.2)                        | 9 (17.6)       | 0.955b  |
| Competent, n (%)                 | 15 (60.0)                   | 15 (57.7)                       | 30 (58.8)      |         |
| Novice, n (%)                    | 6 (24.0)                    | 6 (23.1)                        | 12 (23.5)      |         |
| VAS Score                        |                             |                                 |                |         |
| Median (min–max)                 | 25 (0–100)                  | 18 (0–74)                       | 0.921a         |         |

*a Mann–Whitney test  
*b Chi-Square test  
*c Kolmogorov–Smirnov test  
*d Fischer test
No statistically significant differences between the two groups were observed on both characteristic of subjects, the VAS score and pulsation (Table 2).

**Table 2. Basic Visual Analog Scale (VAS) score and pulsation**

| Values                              | Acupuncture Group (n = 25) | Placebo Puncture Group (n = 26) | p-value |
|-------------------------------------|----------------------------|---------------------------------|---------|
| VAS score before acupuncture        |                            |                                 |         |
| Median (min–max)                    | 0 (0–62)                   | 0 (0–67)                        | 0.468a  |
| Pulsation before acupuncture        |                            |                                 |         |
| Mean (SD)                           | 82.32 (12.76)              | 82.50 (15.836)                  | 0.965b  |

*a* Mann–Whitney Test  
*b* Unpaired *t*-Test

Immediately following the intervention, the median VAS score for the acupuncture group was 29 (Table 3). This score was lower than that of the placebo puncture group (44.5). However, no statistically significant difference was found between the two groups (p = 0.147). During colonoscopy, the mean CPOT value for the acupuncture group (0.92) was lower than that of the placebo puncture group (2.15; p = 0.010). The median CPOT value of the acupuncture group was 0.7, while it was 1.9 in the placebo puncture group. No statistically significant differences in pulsation were observed between the groups during colonoscopy or after intervention: There was a 2.58/min reduction to pulsation in the acupuncture group and a 2.43/min reduction in the placebo puncture group (p = 0.970).

**Table 3. Differences between acupuncture and placebo puncture**

|                                | Acupuncture              | Placebo Puncture           | p-value |
|--------------------------------|--------------------------|----------------------------|---------|
| VAS score immediately after    | 29 (0–00)                | 44.5 (0–100)               | 0.147*  |
| CPOT score during colonoscopy  | 0.7 (0–4.83)             | 1.9 (0–6.20)               | 0.010*  |
| Time needed to reach the cecum during colonoscopy | 16 (8–51) | 22 (5–63) | 0.206* |
| Pulsation changes before and during colonoscopy | −2.58 (14.31) | −2.43 (12.28) | 0.970** |

*a* Mann–Whitney test  
**Unpaired *t*-test

The median time needed to reach the cecum was 16 min in the acupuncture group and 22 min in the placebo puncture group. While the median time in the acupuncture group was lower than that of the placebo puncture group, this difference was not statistically significant (p = 0.206). The side effect emerged because the acupuncture caused a brief moment of pain for one of the 25 subjects (4%) in the acupuncture group. The side effects from the colonoscopy and analgesia occurred more frequently in the placebo puncture group (73.1%) than in the acupuncture group (56%). Two subjects from the acupuncture group (8%) and nine from placebo puncture group (34.6%) felt pain in their stomachs; six subjects (24%) from the acupuncture group and five from the placebo puncture group (19.2%) felt stomachaches.

### 3.2 Discussion

This study, which analyzed data gathered using the VAS and CPOT in addition to measurements of pulsation changes and the time needed to reach the cecum, was the first in Indonesia to administer
auricular acupuncture to patients undergoing colonoscopy. We found that auricular acupuncture was effective at reducing patient pain during endoscopy procedures. Additionally, auricular acupuncture is simple, safe, comfortable for the patient, and does not interfere with the colonoscopy operation system. We applied acupuncture to the MA-TF 1 Shenmen, MA-IC 1 lung, and MA-CW 2 thalamus points based on previous research that reported a reduction to analgesic use post-surgery and knee arthroscopy during their stimulation [10]. Romoli et al., identified the specific MA-SC 4 colon acupuncture point that was included in the present study to achieve better analgesic effects during colonoscopy [11].

The VAS was used in this study because it is generally used to assess pain. The VAS score was measured immediately following colonoscopy by asking each patient how painful the procedure was; however, the midazolam used during the procedure could cause amnesia, and it was therefore necessary to use the right measuring score to assess the pain subjectively. The CPOT (which assesses facial expression, body movement, vocalization, and muscle contraction [12]) was also used in this study because it can be applied to uncommunicative patients who cannot report pain directly. Furthermore, it allows researchers to assess pain without interrupting the procedure, and it is less subjective than the VAS. The assessment system can be implemented easily and has high inter-rater reliability (Cronbach’s α = 0.893), specification (86%), and sensitivity (87%). Several studies have compared the combined use of acupuncture and sedation with the use of sedation in isolation. Fant et al., who divided 30 colonoscopy patients into acupuncture and control groups, found that acupuncture could reduce sedative use during colonoscopy by reducing patient discomfort and anxiety. They applied acupuncture to the LI4, ST36, SP6, SP9, and MA-TF 1 Shenmen ear points 20 min prior to colonoscopy, and continued its use until the end of the procedure. They used electro-acupuncture at 100Hz frequency, the highest intensity that can be used in patients without inducing pain. Midazolam was administered to all subjects before colonoscopy [13].

The current study found the median VAS score to be 29 (0–100) in the acupuncture group and 44.5 (0–100) in the placebo puncture group immediately after colonoscopy. Despite the absence of a statistically significant difference (p = 0.147), the acupuncture group’s lower score might have been caused amnesia—a side effect of midazolam expected to occur in some patients undergoing colonoscopy—which could cause patients to forget the discomfort they experienced during the procedure. To account for this, this study also assessed pain using the CPOT. We found the median CPOT score to be 0.92 (1.09) in the acupuncture group, which was lower than the placebo puncture group’s score of 2.15 (1.74).This result was statistically significant (p=0.010). Colonoscopy is a relatively safe procedure and serious complications, caused by the procedure itself or by the administration of sedatives, are rare. The most common complications found are uncomfortable stomach feeling (25%) and pain or discomfort in the abdomen (5–11%). More serious complications include cardiopulmonary complications (0.9%), colon perforation (0.05–0.07%), hemorrhage (0.1–0.6%), polypectomy electrocoagulation syndrome (0.003–0.1%), gas explosion (extremely rare), and death [14]. Cooper et al., showed that anesthesia increased the risk of complications during colonoscopy (OR=1.46, 95%; CI=1.09–1.94) and found aspiration to occur more frequently in patients that had been administered anesthesia [6]. The side effects of the most commonly used medications include amnesia, analgesia and the anxiolytics effect [15]. The side effects of auricular acupuncture reported by patients (including pain, discomfort, swelling and redness on the acupuncture site, headache, nausea, dizziness and minor inflammation) are comparatively rare, temporary, and tolerable [16].

4. Conclusion
Auricular acupuncture combined with the administration of midazolam and pethidine was effective at reducing pain during colonoscopy.

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