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Effect of cocktail therapy after arthroscopic rotator cuff repair: a randomized, double-blind trial

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Background: We investigated the effectiveness of cocktail therapy after arthroscopic rotator cuff repair (ARCR).
Methods: We evaluated 128 shoulders undergoing ARCR and used block randomization to divide patients into 2 groups in this double-blind trial: The cocktail group received 20 mL of 0.75% ropivacaine, 5 mg of morphine, 0.3 mg of epinephrine, 2 mg of betamethasone, and saline solution to a total of 42 mL, whereas the control group received 20 mL of 0.75% ropivacaine and saline solution to a total of 42 mL. Postoperatively, one of the drug mixtures was injected into the glenohumeral joint, subacromial bursa, suprascapular nerve, and anterior, middle, and posterior parts of the deltoid muscle according to the treatment group. We recorded patients' visual analog scale scores preoperatively and at 4, 8, 16, 24, and 48 hours postoperatively; the number of patients using postoperative diclofenac suppositories and buprenorphine hydrochloride; the number of patients experiencing nausea; the number of patients with infection and delayed wound healing as adverse effects; the surgery time; the retear rate; and passive shoulder range of motion.
Results: The cocktail group constituted 64 shoulders (50.0%), with 39 men (60.9%) and 25 women (39.1%); the mean age was 64.2 ± 10.2 years. The control group constituted 64 shoulders (50.0%), with 41 men (64.1%) and 23 women (35.9%); the mean age was 65.2 ± 7.5 years. We found no significant difference in age or sex between the 2 groups. There was also no significant difference in rotator cuff tear size or surgery time between the 2 groups. The visual analog scale scores at 8, 16, and 24 hours postoperatively were significantly lower in the cocktail group. The number of patients using suppositories was also significantly lower in the cocktail group. The number of patients receiving buprenorphine injections tended to be lower in the cocktail group, but the difference was not significant. Nausea occurred in 6.3% of patients in the cocktail group and 15.6% in the control group, but the difference was not significant. No infection or delayed wound healing occurred in either group. There was no significant difference in the retear rate between the 2 groups. Passive anterior elevation at 3 months postoperatively was significantly better in the cocktail group than in the control group.
Conclusion: We compared cocktail therapy and ropivacaine after ARCR and found no difference in results except for VAS score at 8, 16, and 24 hours postoperatively and frequency of postoperative suppository use without an apparent risk of infection or a detrimental effect on tendon healing.
Level of evidence: Level II; Randomized Controlled Trial; Treatment Study

Keywords: Arthroscopic rotator cuff repair; interscalene block; suprascapular nerve block; cocktail therapy; postoperative pain management; visual analog scale

Arthroscopic surgery has made it possible to perform minimally invasive surgery for rotator cuff tears (RCTs), but postoperative pain management is extremely important for early recovery.[2,16] As pain management for shoulder arthroscopic surgery, local anesthetic blocks such as the

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single-dose interscalene block[2] and suprascapular nerve (SSN) block[15] are combined with general anesthesia preoperatively, and the single-dose or continuous glenohumeral joint block, subacromial bursa (SAB) block,[16] continuous intravenous opioid injections, and continuous interscalene[2] and continuous SSN blocks[3,4,12] are administered postoperatively.

Recently, periarticular cocktail therapy has been performed as pain management after total knee arthroplasty and total hip arthroplasty, and its effects have been reported.[5,14] The purpose of this study was to investigate the effectiveness of cocktail therapy combined with single-dose interscalene and SSN blocks after arthroscopic rotator cuff repair (ARCR). We hypothesized that cocktail therapy combined with single-dose interscalene and SSN blocks would provide better pain management than single-dose interscalene and SSN blocks alone after ARCR.

Materials and methods

We evaluated 128 shoulders in patients who underwent ARCR at a single institution from July 2017 to October 2018. Using block randomization, we divided the shoulders into 2 groups in this double-blind trial: The cocktail group received a mixture of 20 mL of 0.75% ropivacaine, 5 mg of morphine, 0.3 mg of epinephrine, 2 mg of betamethasone, and saline solution to a total of 42 mL, whereas the control group received 20 mL of 0.75% ropivacaine and saline solution to a total of 42 mL. We defined the term ''cocktail'' in this study as a mixture of a local anesthetic, narcotic, catecholamine, corticosteroid, and saline solution. We did not use betamethasone in patients with a history of diabetes (hemoglobin A_{1c} level $\geq$ 7.0%; cocktail group, n = 3; control group, n = 1), morphine in patients with a history of asthma (n = 0), or epinephrine in patients with glaucoma (n = 0). The types and amounts of drugs were determined with reference to a study by Ranawat and Ranawat,[14] but we created original mixtures of drugs and decreased their amounts because the shoulder joint is smaller than the knee joint. We injected each of 6 locations with 7 mL of drug solution according to the treatment group: the glenohumeral joint; the SAB using an arthroscope without Arthromatic sodium chloride irrigant (Baxter Healthcare, Deerfield, IL, USA) if possible; the SSN (the dominant nerve of the supraspinatus and infraspinatus muscles) using landmarks that had been created during the preoperative ultrasound-guided SSN block; and the anterior, middle, and posterior fibers of the deltoid muscle around the portals, respectively. The injection sites of the deltoid muscle were checked directly after skin closure. Fentanyl, the dose of which was corrected for weight, was intravenously administered continuously for 20 hours postoperatively in all patients. In addition, diclofenac suppositories (25 mg in patients with a body weight $<$ 50 kg and 50 mg in patients with a body weight $\geq$ 50 kg) were repeatedly administered at intervals of $\geq$6 hours as additional analgesia at the patients' request. Buprenorphine injections (0.2 mg) were administered, if required, within 6 hours of diclofenac suppository administration. From the day after surgery, pain management was performed by administering nonsteroidal anti-inflammatory drugs at 180 mg/d for 7 days and tramadol hydrochloride at 37.5 mg/d for 14 days in all patients.

Study variables

Demographic variables

The demographic variables evaluated in both groups were age at the time of surgery, sex, RCT size[7] measured intraoperatively, and surgery time.

Evaluated parameters

We evaluated patients' visual analog scale (VAS) scores preoperatively and at 4, 8, 16, 24, and 48 hours postoperatively; the number of patients using postoperative diclofenac suppositories; the number of patients receiving buprenorphine injections; and the number of patients experiencing nausea, infection, and delayed wound healing as adverse effects. We also evaluated the retear rate after ARCR. Retears were defined as types 4 and 5 of the classification established by Sugaya et al[18] and were assessed by magnetic resonance imaging at 6 months postoperatively. Finally, we evaluated passive shoulder range of motion (ROM) including anterior elevation (AE) and external rotation with the arm at the side preoperatively and at 3 and 6 months postoperatively. We compared these items prospectively between the 2 groups.

Surgical procedure

All operations were performed by the author (T.T.) with patients under general anesthesia and receiving an ultrasound-guided single-dose interscalene block (35 mL of 0.375% ropivacaine) and an SSN block (5 mL of 0.375% ropivacaine) in the beach-chair position. Depending on the size of the RCT, we performed a single-row repair for partial tears of the supraspinatus and infraspinatus tendons and grade 1 subscapularis tendon tears according to the classification established by Lafosse et al[11] (cocktail group, n = 31 [48.4%]; control group, n = 37 [57.8%]). We performed the conventional suture bridge repair for all complete tears of the supraspinatus and infraspinatus tendons and grade $\geq$2 subscapularis tendon tears according to the classification established by Lafosse et al (cocktail group, n = 8 [12.5%]; control group, n = 6 [9.4%]). Subacromial decompression and anterior acromioplasty were performed in all patients. We performed long head of the biceps tendon tenotomy (cocktail group, n = 16 [25.0%]; control group, n = 10 [15.6%]) or tenodesis (cocktail group, n = 1 [1.6%]; control group, n = 0 [0.0%]) in patients with a positive hourglass test result and in patients with dislocation or subluxation of the long head of the biceps tendon as detected from the bicipital groove. There were no significant differences between the 2 groups in the numbers of biceps tendon tenotomy or tenodesis procedures or in the subscapularis tendon repair rate (cocktail group, n = 39 [60.9%]; control group, n = 43 [67.2%]).

Postoperative rehabilitation

Sling immobilization was performed for 5 weeks postoperatively, and passive ROM exercise was started at 3 weeks postoperatively. Active-assisted ROM exercise was started at 6 weeks postoperatively, and active ROM exercise was permitted beginning at 7 weeks postoperatively. Therapy was delayed 1 week in patients with larger than medium-sized RCTs. The surgery was performed on an inpatient basis. Discharge from the hospital was allowed after the sling immobilization was released at 5 weeks

Table I Patients' demographic variables

	Cocktail group	Control group
n (%)	64 (50.0)	64 (50.0)
Mean age at surgery (range), yr	64.2 ± 10.2 (38-84)	65.2 ± 7.5 (45-83)
Male/female sex, n (%)	39 (60.9)/25 (39.1)	41 (64.1)/23 (35.9)
Tear size, n (%)		
Medium	47 (73.4)	50 (78.1)
Large	17 (26.6)	14 (21.9)
Surgery time, min	94.1	88.4

postoperatively. There was no significant difference in the length of hospital stay between the two groups.

Statistical analysis

We used the Mann-Whitney test to compare differences in outcomes between the 2 groups. SPSS Statistics for Windows (version 20.0; IBM, Armonk, NY, USA) was used for all statistical analyses. The level of statistical significance was set at $P < .05$, and the results are presented as mean values.

Results

Patients' demographic variables

The cocktail group constituted 64 shoulders (50.0%), with 39 men (60.9%) and 25 women (39.1%); the mean age was 64.2 ± 10.2 years. The control group constituted 64 shoulders (50.0%), with 41 men (64.1%) and 23 women (35.9%); the mean age was 65.2 ± 7.5 years. We found no significant difference in age or sex between the 2 groups. There was also no significant difference in RCT size or surgery time between the groups (Table I).

VAS scores and postoperative pain management

VAS scores were similar between the 2 groups before surgery but were lower in the cocktail group from 4 to 48 hours after surgery. In addition, VAS scores were significantly lower in the cocktail group from 8 to 24 hours after surgery (Fig. 1). The number of patients using postoperative diclofenac suppositories was significantly lower in the cocktail group: 9 shoulders (14.1%) in the cocktail group and 25 shoulders (39.1%) in the control group. The average number of times patients used diclofenac suppositories was 1.11 in the cocktail group and 1.38 in the control group, and 1 patient in the control group used diclofenac suppositories more than 3 times. The number of patients receiving buprenorphine injections tended to be lower in the cocktail group than in the control group (0

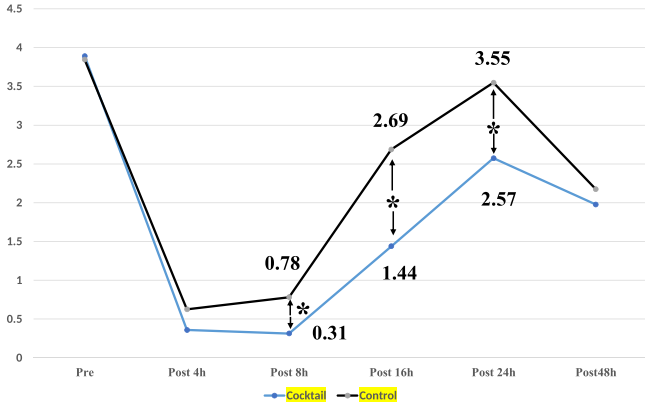

Figure 1 Preoperative (Pre) and postoperative (Post) visual analog scale scores between the 2 groups. *h*, hours. * Statistically significant difference ($P < .05$).

shoulders [0.0%] vs. 3 shoulders [4.7%]), but the difference was not significant (Table II).

Adverse effects and complications

Nausea occurred in 4 shoulders (6.3%) in the cocktail group and 10 shoulders (15.6%) in the control group, but the difference was not significant. There were no cases of infection or delayed wound healing in either group (Table II).

Retear rate after ARCR

There were no significant differences in the retear rate of the supraspinatus and infraspinatus tendons (cocktail group, n = 2 [3.1%]; control group, n = 3 [4.7%]) or subscapularis tendon (cocktail group, n = 0 [0.0%]; control group, n = 0 [0.0%]).

Passive shoulder ROM

Passive shoulder ROM, including AE and external rotation with the arm at the side, were similar in the 2 groups before surgery. Passive AE at 3 months postoperatively was significantly better in the cocktail group (151.6°) than in the control group (145.9°). There were no significant differences in passive shoulder ROM at 6 months postoperatively between the 2 groups (Table III).

Discussion

In this study, because there was no significant difference in age, sex, RCT size, or surgery time between the 2 groups, it was possible to eliminate the effects of these factors and to examine the effectiveness of cocktail therapy combined with single-dose interscalene and SSN blocks after ARCR. Pain management after shoulder arthroscopic surgery has

Table II Postoperative use of analgesics and incidence of nausea

	Cocktail group	Control group
Diclofenac suppository use, n (%)	9 (14.1)	25 (39.1)*
Average frequency of diclofenac suppository use	1.11	1.38
Buprenorphine injection use, n (%)	0 (0)	3 (4.7)
Nausea, n (%)	4 (6.3)	10 (15.6)
Infection, n (%)	0 (0)	0 (0)
Delayed wound healing, n (%)	0 (0)	0 (0)

* Statistically significant difference ($P < .05$).

been reported to affect postoperative rehabilitation and is therefore important.[2,16] However, it is difficult to manage postoperative pain with nonsteroidal anti-inflammatory drugs alone, and these must be combined preoperatively with local anesthetic blocks such as interscalene and SSN blocks in patients undergoing general anesthesia.[2,15] Postoperatively, single-dose or continuous glenohumeral joint blocks or SAB blocks,[16] continuous intravenous opioid injections, and continuous interscalene[2] and continuous SSN blocks[3,4,12] have been used in combination. Traditionally, we performed postoperative pain management using preoperative single-dose interscalene blocks, SSN blocks, and continuous intravenous fentanyl administration postoperatively. Although these therapies alleviate postoperative pain, a single-dose interscalene block lasts for only approximately 10 hours (however, large variation in the duration of a single-dose interscalene block has been seen, and such blocks may last >10 hours). Therefore, patients require additional pain management from the night of surgery to the next postoperative day. To address this need, continuous administration of a local anesthetic into the glenohumeral joint and an SAB or continuous interscalene and/or SSN block can be used. However, cartilage lysis has been reported after continuous administration of local anesthesia into the glenohumeral joint[8,20]; therefore, this therapy is not recommended. In addition, although a continuous interscalene block is effective, this method is invasive and the frequency of complications such as phrenic nerve palsy is high.[8,10]

Ranawat and Ranawat[14] recently reported that cocktail therapy was effective for postoperative pain management after total knee arthroplasty and total hip arthroplasty. Busch et al,[5] using cocktail therapy for total knee arthroplasty, reported that the amount of analgesic used was low up to 24 hours after surgery. Hence, the effectiveness of postoperative cocktail therapy has been reported for both total knee arthroplasty and total hip arthroplasty. In our study, adding cocktail therapy to the single-dose interscalene and SSN blocks was effective because this relieved pain after the effect of these blocks dissipated. In addition, the frequency of diclofenac suppository use decreased significantly postoperatively, similarly to the results reported by Busch et al.

Although nausea can occur when using morphine in cocktail therapy and administering fentanyl postoperatively, nausea occurred in only 4 patients (6.3%) in the cocktail group and in 10 patients (15.6%) in the control group. Because it occurred more frequently in the control group, nausea as an adverse effect of morphine in the cocktail therapy was considered minor. With respect to the development of infection and the detrimental effects of betamethasone in the glenohumeral joint and SAB immediately after ARCR, Perdreau and Joudet[13] performed intra-articular injections of morphine plus methylprednisolone after ARCR and found no cases of superficial infection or delayed wound healing. Likewise, Cho et al[6] found no cases of superficial or deep infection or delayed healing during 3 months of follow-up after ARCR despite the use of corticosteroid doses that were 3-fold higher. We also encountered no cases of superficial infection in either group and no significant differences in the retear rate of the supraspinatus, infraspinatus, or subscapularis tendons. These findings indicate that injection of morphine plus methylprednisolone into the joint and SAB immediately after ARCR seems to have little detrimental effect on rates of infection and tendon healing.

When single-dose nerve blocks are used, strong pain appears when the effect of the nerve block dissipates, and studies have shown that the pain at this time is stronger than that in patients not receiving these nerve blocks. This phenomenon is called "rebound pain" and is a problem in perioperative pain management using a single-dose nerve block.[1,9] No apparent rebound pain was observed in either group in this study because we used analgesics such as opioids well before the effect of the single-dose interscalene and SSN blocks dissipated, which is a reported remedy for rebound pain.[17,19] Moreover, adding drugs other than local anesthetics may prolong the duration of the nerve blocks.[19] We believe that our patients experienced no rebound pain because we used opioids postoperatively in both groups and added drugs to the local anesthetics in the cocktail group. The lack of rebound pain also suggested the effectiveness of cocktail therapy.

With respect to early recovery of passive shoulder ROM after postoperative pain management using cocktail therapy in patients who have undergone ARCR, we found significantly earlier recovery of passive AE in the cocktail group than in the control group at 3 months postoperatively. Although there were no significant differences in shoulder ROM at 6 months postoperatively, cocktail therapy was considered effective in terms of early recovery.

Our results showed that it was possible to relieve pain by adding a very simple cocktail therapy to the single-dose interscalene and SSN blocks after ARCR without causing serious adverse effects. This approach also relieved patients' postoperative pain when the effect of the single-dose

Table III Preoperative and postoperative passive shoulder range of motion

	Preoperative	Postoperative	
		3 mo	6 mo
Anterior elevation, °			
Cocktail group	145.3 ± 18.4 (120-170)	151.6 ± 13.5 (120-175)*,†	154.3 ± 12.3 (120-175)*
Control group	146.7 ± 22.6 (80-170)	145.9 ± 17.0 (100-170)	151.7 ± 13.2 (100-175)*
External rotation with arm at side, °			
Cocktail group	54.3 ± 17.1 (0-85)	48.3 ± 11.5 (25-65)	49.5 ± 11.2 (25-65)
Control group	57.5 ± 14.7 (10-85)	46.6 ± 10.0 (25-65)	47.6 ± 9.0 (40-65)

Data are expressed as mean ± standard deviation (range).
* Statistically significant difference between preoperative and postoperative values ($P < .05$).
† Statistically significant difference between groups ($P < .05$).

interscalene and SSN blocks dissipated. In addition, the frequency of postoperative analgesic use was reduced. The pain-relief approach in this study was useful for postoperative pain management after ARCR.

This study is not without limitations. First, the effects of cocktail therapy alone are unclear, but we believe that a synergistic effect could be expected by adding cocktail therapy to the single-dose interscalene and SSN blocks. Second, adverse effects to the nerves secondary to the drug mixture in the cocktail are unknown. Third, the VAS scores after 48 hours were not evaluated. Finally, because the ideal injection points and drug solution volumes in cocktail therapy have not been established, further studies are needed to determine safe and effective guidelines.

Conclusion

We compared cocktail therapy and ropivacaine after ARCR and found no difference in results except for VAS score at 8, 16, and 24 hours postoperatively and frequency of postoperative suppository use. Cocktail therapy combined with single-dose interscalene and SSN blocks was useful for postoperative pain management after ARCR without an apparent risk of infection or detrimental effect on tendon healing in this study.

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