1-1-2022

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JSES International 6 (2022) 104–110

Contents lists available at ScienceDirect

JSES International

journal homepage: www.jsesinternational.org

Efficacy of transdermal 4% lidocaine patches for postoperative pain management after arthroscopic rotator cuff repair: a prospective trial

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ARTICLE INFO

Keywords:
Lidocaine
Rotator cuff
Analgesia
Shoulder
Surgery
Repair
Pain

Level of evidence: Level II; Randomized Controlled Trial; Treatment Study

Background: Postoperative pain management continues to be a challenging aspect of patient care. Lidocaine patches have shown efficacy in reducing pain in other surgical specialties and mixed results in orthopedic trials. We sought to determine the effectiveness of nonprescription lidocaine patches in reducing postoperative pain after arthroscopic rotator cuff repair

Methods: Patients undergoing primary arthroscopic rotator cuff repair were recruited from 3 surgeons at a single institution. All patients of each surgeon were randomized to a lidocaine patch or control group, with crossover occurring at the midpoint. Experimental group patients received 26 4% lidocaine gel-patches. They were provided written and visual instructions to begin wearing the lidocaine patches during daytime on postoperative day (POD) 2. They were to be switched every 8 hours and removed overnight. Control group patients received normal standard of care but did not receive a placebo control. Exclusion criteria included workmen's compensation claims, age <18 years, history of myocardial infarction, and history of lidocaine or adhesive allergies. The American Shoulder and Elbow Surgeons shoulder survey was completed preoperatively and 2-, 6-weeks, 3-, 4.5-, and 6-months postoperatively. A 14-day visual analog scale pain and medication log was completed three times daily following repair. All patients received interscalene nerve block with bupivacaine and general anesthesia.

Results: 80 (40 control, 40 lidocaine) patients were enrolled, with 53 completing follow-up. Groups were demographically similar in age ($P = .22$), gender ($P = .20$), and body mass index ($P = .77$). They were similar in tear pattern ($P = .95$), concomitant acromioplasty ($P = .44$), concomitant biceps tenodesis ($P = .07$), and number of anchors used ($P = .25$). There was no difference in American Shoulder and Elbow Surgeons scores at any time points (range $P = .28$-$P = .97$). Reported 14-day pain logs were not different between study groups at any time points (range $P = .07$-$P = .99$). There was no difference in opioid consumption in the first 14 days after surgery ($P = .38$). The lidocaine group reported less satisfaction with their pain management beginning in the evening of POD 2 ($P = .05$). This continued until the afternoon of POD 8 ($P = .03$).

Conclusion: Transdermal 4% lidocaine patches are not effective in reducing pain or opioid consumption after arthroscopic rotator cuff repair and were associated with reduced patient satisfaction.

Although orthopedic surgeons continue to improve functional outcomes and surgical technique in rotator cuff repair, postoperative pain management continues to be a challenging aspect of patient care. Opioid medications are often the first-line treatment for postoperative pain; however, they are associated with deleterious effects such as constipation, respiratory depression, and dependence. Multiple strategies have been investigated to decrease the need for narcotic use after surgery. One strategy that warrants investigation is the use of transdermal lidocaine patches.

Lidocaine patches allow for the local absorption of lidocaine into a specific area. The lidocaine inhibits neuron activity, temporarily relieving pain. Five-percent prescription lidocaine patches have received Food and Drug Administration approval for post-herpetic neuralgia; however, both prescription and nonprescription patches have been used off-label for relief of pain secondary to other conditions. Although it is commonly thought that only superficial pain can be mediated by patches, there is evidence that 'deeper' nerve pain may be alleviated by 5% transdermal lidocaine (T5L) patches as

Jefferson Institutional Review Board approved this study (18D.755).

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https://doi.org/10.1016/j.jseint.2021.09.006

well.[6] This has spurred interest in the use of T5L to alleviate pain secondary to trauma and surgery, across multiple disciplines.[3,8,11-13,15] In orthopedics, clinical trials evaluating the use of T5L after total knee arthroplasty have shown mixed results. A randomized trial evaluating the use of T5L after arthroplasty found decreased pain at 1 day, 2 days, 3 days, and 2 weeks postop, as well as decreasing opioid medication consumption.[14] In contrast, another study investigating the use of T5L during inpatient rehabilitation after total knee arthroplasty (TKA) found that there was actually an increase in pain associated with T5L patch use.[10]

Pain management after arthroscopic rotator cuff repair is largely dependent on opioid medication use and a nerve blockade in the immediate postoperative period. Identification of effective non-opioid pain management modalities, such as lidocaine patches, is essential for the improvement of postoperative pain management. There is some evidence that over-the-counter lidocaine patches may be equal in efficacy to T5L.[2] If nonprescription lidocaine patches can decrease postoperative pain, they would serve as an easily accessible and inexpensive option. The aim of this study was to evaluate the effectiveness of nonprescription lidocaine patches in reducing postoperative pain after arthroscopic rotator cuff repair. A secondary aim was to evaluate the effectiveness of lidocaine patch therapy in reducing opioid consumption. We hypothesized that the use of lidocaine patches would decrease postoperative pain and opioid consumption after arthroscopic rotator cuff repair.

Methods

Study protocol was approved by our institutional review board before voluntary patient enrollment. This was a prospective, provider cross-over design trial performed at a single institution to determine the efficacy of transdermal lidocaine patches in controlling postoperative pain. Eighty patients undergoing primary arthroscopic rotator cuff repair with one of three board-certified, fellowship-trained, sports medicine orthopedic surgeons were recruited. Exclusion criteria included the following: (1) age under 18 years old, (2) pregnancy, (3) patients with known lidocaine or adhesive allergies, (4) patients with history of cardiac arrhythmias or myocardial infarction, (5) irreparable tears, and (6) patients with workmen's compensation claim or pending litigation.

Treatment

There were two arms to this study, experimental and control. All patients received general anesthesia and a liposomal bupivacaine interscalene nerve block, performed by a board-certified anesthesiologist. The postoperative medication regimen consisted of 30 oxycodone 10-mg tablets and Zofran 4-mg tablets. Cryo cuff and nonsteroidal anti-inflammatory drug usage was allowed. All patients were treated with a uniformly homogenous therapy program. Sling immobilization was carried out for 4 weeks after surgery, with passive range of motion allowed out of the sling during this initial phase. After 4 weeks, the sling was discontinued, and active assisted range of motion was allowed with progression to active range of motion by 8 weeks. At 10 weeks after surgery, patients were begun on a progressive strengthening program which was continued until 16 weeks after surgery, at which time patients were transitioned to a home exercise program. Release to full activity was permitted at 6 months after surgery.

The experimental group received 26 Salonpas (Hisamitsu Co., Tosu, Japan) 4% lidocaine gel patches. They were provided with a printed page of instructions on how and when to apply patches (Supplementary Appendix S1), in addition to a verbal explanation at the time of enrollment. Instructions described cutting the patch in half and applying them superiorly and inferiorly to the arthroscopic portal sites. Beginning on postoperative day (POD) 2, experimental group patients were instructed to wear the lidocaine patches during daytime through POD 14. They were to be switched every 8 hours and removed overnight. Control group patients received normal standard of care; they did not receive placebo patches.

Patient recruitment and group assignment

Patient eligibility screening was performed by research staff who played no role in clinical care. Eligible patients were interviewed by the same research staff to verify eligibility in private, clinical examination rooms. Patients were assigned to treatment groups based on their surgeon. Individual surgeons were randomly assigned to one of two treatment arms at the onset of the study and blinded to assignment. If a surgeon was assigned to the experimental group, all enrolled patients of that surgeon received lidocaine patches. At the midpoint of enrollment, surgeons switched treatment arms. If a surgeon's patients were formerly receiving lidocaine patches, for the remainder of the study, the enrolled patients for that surgeon were in the control group. Patients were blinded to the other arm of the study. Informed consent was obtained in accordance with institutional review board–approved consent forms. Patients were debriefed about the intent of the study and group assignment at their 6-week follow-up visit with a preapproved debriefing script.

Outcome measures

Patients in both groups were asked to complete the American Shoulder and Elbow Surgeons (ASES) Standardized Shoulder Assessment Form preoperatively and at 2 weeks, 6 weeks, 3 months, 4.5 months, and 6 months postoperatively. They were also asked to complete a custom 5-question visual analog scale pain and opioid medication log 3 times daily (morning, afternoon, and evening), POD 0-POD 14. Average pain, pain at rest, pain with activity, and satisfaction with pain management were assessed. Opioid medication usage and dosing were also to be logged. Preoperative and long-term usage of analgesics was compared using ASES questionnaire item 4: "Do you take pain killers such as paracetamol (acetaminophen), diclofenac, or ibuprofen?" and item 5: "Do you take strong pain killers such as codeine, tramadol, or morphine?". Patient demographics of age, gender, and body mass index (BMI) were collected as well. A minimal clinically important difference (MCID) of 1.5 was used to compare pain scores.[4] An MCID of 26.9 was used to compare ASES scores.[5]

Power statistical analysis

Sample size was determined using the MCID for visual analog scale postoperative pain scores, 80% power, and prior clinical data. A total of 29 patients in each group were needed to achieve 80% power. This was increased to 40 in each group to account for attrition. Statistical analysis was performed by a statistician who is independent of the research team. Categorical data were analyzed with chi-squared tests, and continuous data were analyzed with *t*-tests or Mann-Whitney tests. A P value of $<.05$ was considered significant.

Results

Study population

Eighty patients were enrolled in this study. Twenty-seven (34%) of the study population were excluded from final analysis. One patient had an allergic reaction from hives and discontinued study

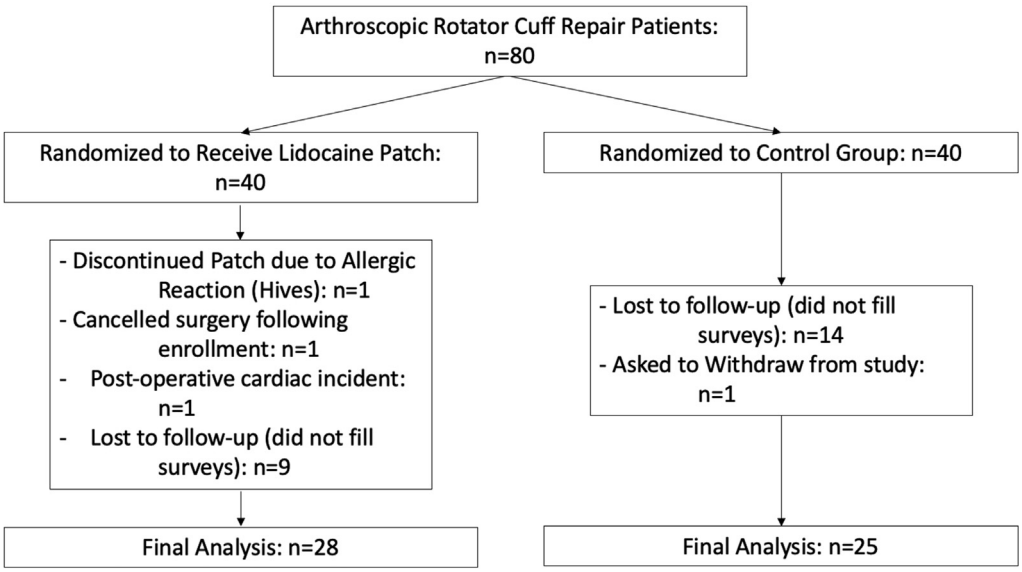

Figure 1 CONSORT diagram.

participation. One patient had postoperative atrial fibrillation and was asked not to start lidocaine patch usage. One patient canceled surgery after enrollment. One patient asked to withdraw from the study after enrollment. Twenty-three patients were lost to follow-up or had incomplete recording of data (Fig. 1).

The 53 patients included for final analysis consisted of 28 male and 25 female patients with a mean age of 61.5 ± 9.5 and a mean BMI of 30.2 ± 5.9. The 27 patients excluded from analysis consisted of 12 male and 15 female patients with a mean age of 61.3 ± 8.9 and a mean BMI of 27.6 ± 4.7. There was no difference in demographics between patients who completed follow-up and those who did not. The experimental group had 17 male and 11 female patients with a mean age of 59.9 ± 11.3 and a mean BMI of 30.5 ± 6.7. The control group had 11 male and 14 female patients with a mean age of 63.3 ± 6.9 and a mean BMI of 30.0 ± 5.0. Demographics were similar between the treatment and control groups (Table I).

There were no statistical differences between the treatment and control groups with regard to arthroscopically confirmed rotator cuff tear pattern, concomitant procedures (acromioplasty, biceps tenodesis), or number of suture anchors used (Supplementary Appendix S3). There were three partial thickness supraspinatus tears, thirteen full thickness supraspinatus tears, six full thickness supraspinatus tear + partial thickness tears of an additional tendon, and six full thickness of two or more tendons in the treatment group. There were two partial thickness supraspinatus tears, eleven full thickness supraspinatus tears, seven full thickness supraspinatus tear + partial thickness tears of an additional tendon, and five full thickness of two or more tendons in the control group. Concomitant acromioplasty was performed in 13 of treatment group patients vs. 9 of the control. Biceps tenodesis was performed in 10 of the treatment group vs. 15 of the control. In the treatment group, there were 2 zero-anchor (collagen patch), 5 two-anchor, 11 three-anchor, 4 four-anchor, 2 five-anchor, 1 six-anchor, and 3 seven-anchor repairs performed. In the control group there were 0 zero-anchor (collagen patch), 8 two-anchor, 8 three-anchor, 7 four-anchor, 2 five-anchor, 0 six-anchor, and 0 seven-anchor repairs performed.

Functional outcomes

Preoperatively, the mean experimental group ASES score was not different from the control group (50.7 ± 26.1 vs. 43.2 ± 13.8; $P = .31$). There was also no difference between groups at the 2-week, 6-week, 3-month, 4.5-month, and 6-month follow-up surveys (Table II). At 6 months postoperatively, the mean ASES score for the experimental group and control group was 88.1 ± 11.7 and 89.6 ± 8.9 ($P = .68$), respectively. Both groups demonstrated improvement in ASES scores at 6 months postoperatively, compared with preoperative scores ($P < .01$ for both). ASES improvement for both groups exceeded the MCID of 26.9 (Table II).

Pain management

Preoperatively, there was no difference in reported “pain medication” use such as paracetamol (acetaminophen), diclofenac, or ibuprofen ($P > .99$). There was also no difference in reported “strong pain killer” usage such as codeine, tramadol, or morphine ($P > .99$). At 2 weeks, the experimental group reported taking more

Table I
Patient demographics.

Demographics	Lidocaine (n = 28)	Control (n = 25)	*P* values	Excluded (n = 27)
Gender (M/F)	17/11	11/14	.20	12/15
Age (y)	59.89 (±59.89)	63.32 (±6.91)	.22	61.33 (±8.89)
BMI (kg/m)	30.46 (±6.68)	29.99 (±5.04)	.77	27.61 (±4.65)

BMI, body mass index.
Data presented as mean ± standard deviation.
P values represent comparisons between the lidocaine and control groups.

Table II
ASES score.

Time point	Lidocaine	Control	*P* values
Preoperative	50.68 (±26.14)	43.22 (±13.75)	.31
2 weeks	47.09 (±19.81)	45.10 (±11.91)	.69
6 weeks	57.86 (±17.32)	57.64 (±16.38)	.97
3 months	75.95 (±19.27)	73.94 (±17.40)	.75
4.5 months	80.68 (±16.10)	85.88 (±12.59)	.28
6 months	88.12 (±11.71)	89.55 (±8.87)	.68

ASES, American Shoulder and Elbow Surgeons.
Data presented as mean ± standard deviation.

Table III
Opioid usage.

Usage duration	Lidocaine (n = 28)	Control (n = 25)	*P* value
Day 0 + 1	12.46 (±13.70)	9.3 (±14.89)	.43
Day 2-14	68.57 (±94.62)	49.35 (±79.43)	.43
Total cumulative	81.03 (±95.11)	58.65 (±87.50)	.38

Data in morphine milligram equivalents.

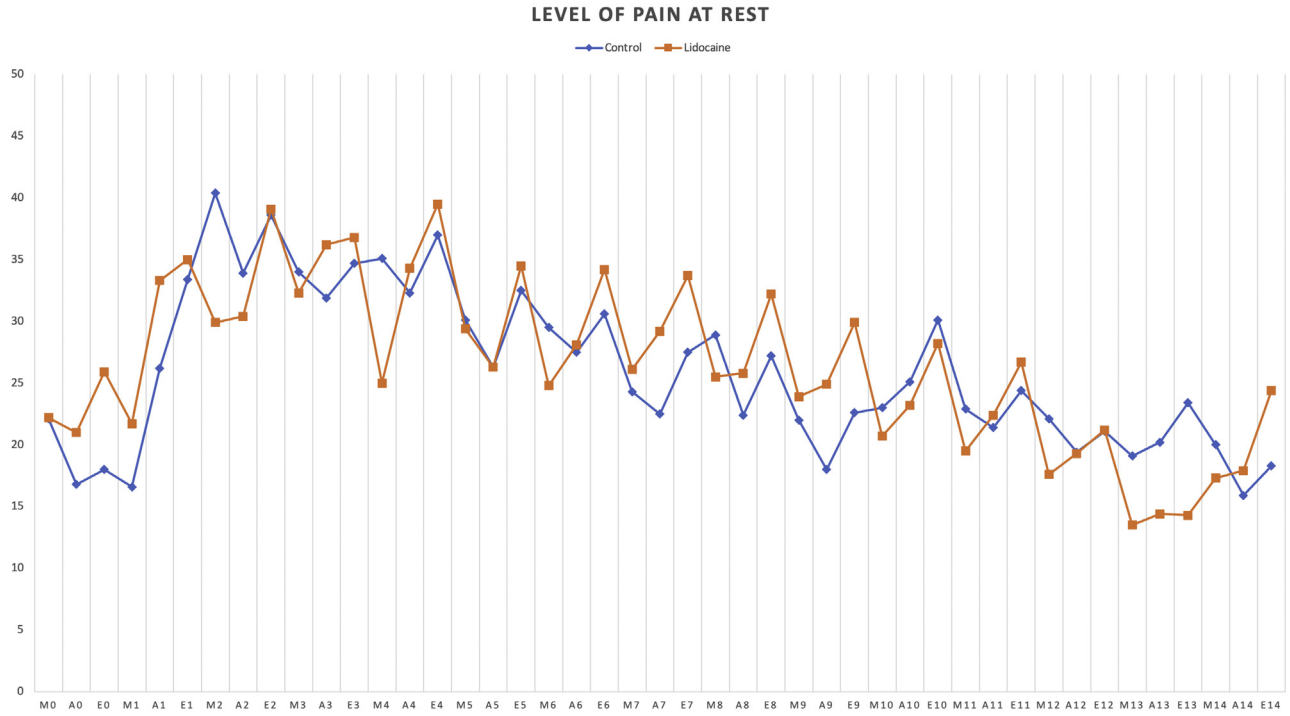

Figure 2 Reported pain levels at rest. *M*, morning; *A*, afternoon; *E*, evening.

"pain medications" overall ($P = .04$), but not "strong pain killers" ($P = .08$). This difference resolved by 6 weeks ($P = .17$) and remained nondifferent up to 6 months postoperatively.

Reported opioid medications were converted into morphine milligram equivalents (MMEs). Cumulative MME consumption from POD 0 and POD 1, before the experimental group initiating lidocaine patch therapy, was not different between groups ($P = .43$). Day 2-14, after lidocaine patch therapy, demonstrated no difference between groups for cumulative MME consumed ($P = .43$). Total cumulative MME consumption was not different between groups ($P = .38$) (Table III).

Reported pain levels and satisfaction were compared for each distinct asked question (pain at rest, pain with activity, average pain, satisfaction with pain management) at each time point (Supplementary Appendix S2). There were no differences between groups for pain at rest, pain with activity, and average pain for any time point from POD 0 to POD 14 (Figs. 2-4). The experimental group reported less satisfaction with their pain management, beginning in the evening of POD 2 (83.0 ± 24.8 vs. 64.4 ± 34.2; $P = .05$). This continued until the afternoon of POD 8 (84.0 ± 26.2 vs. 62.1 ± 35.2; $P = .03$) and recurred one more time in the evening of POD 9 (85.4 ± 24.1 vs. 66.8 ± 33.8; $P = .04$) (Fig. 5).

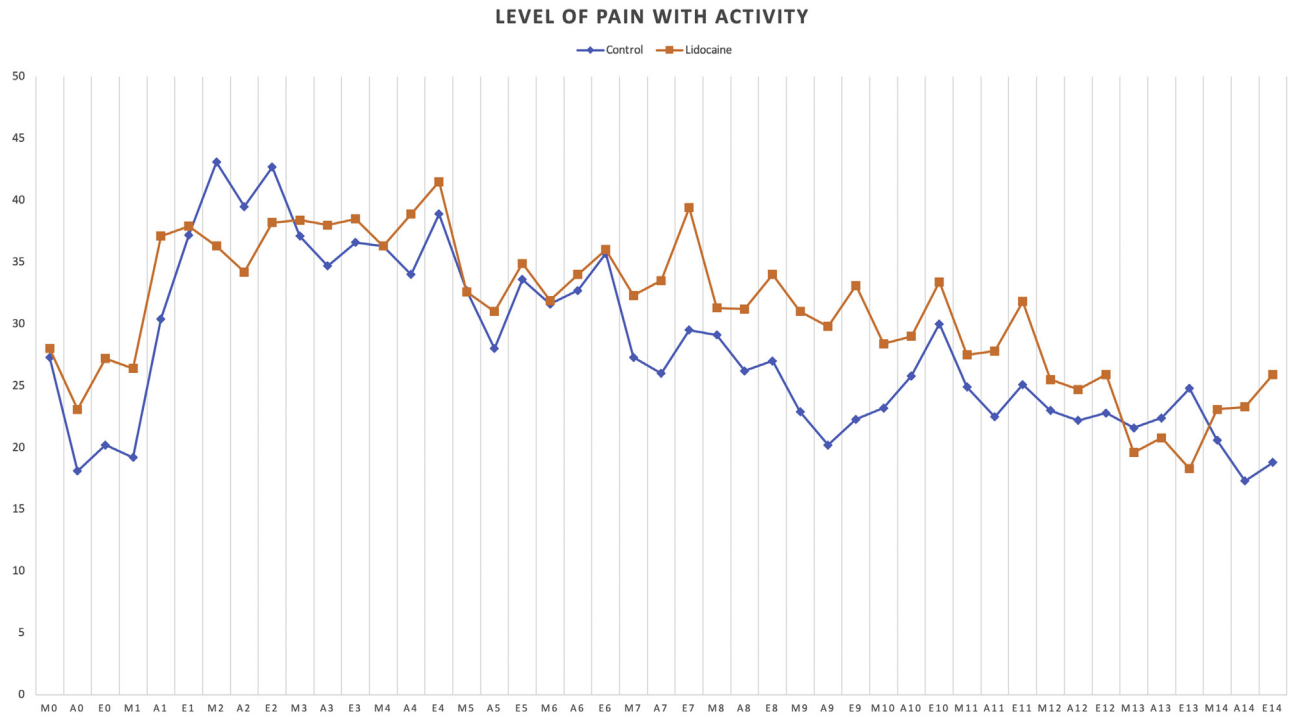

Figure 3 Reported pain levels with activity. *M*, morning; *A*, afternoon; *E*, evening.

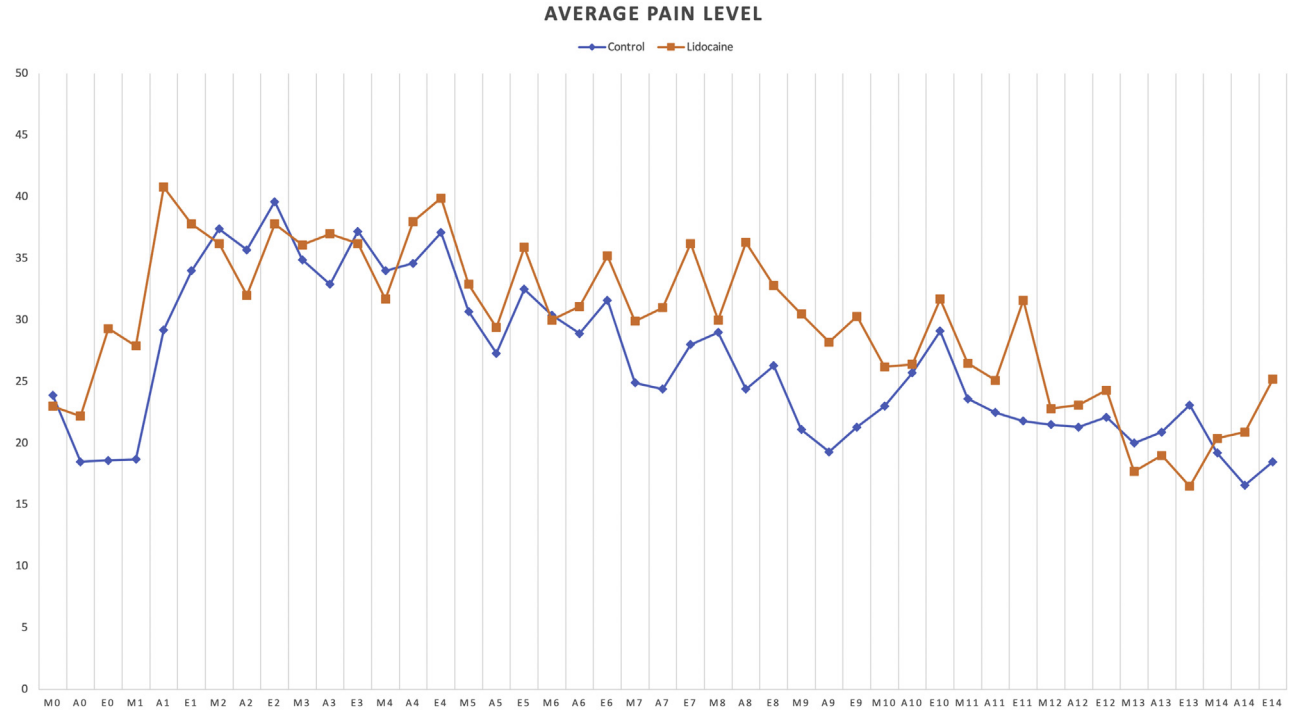

Figure 4 Reported average pain level. *M*, morning; *A*, afternoon; *E*, evening.

Discussion

There is evidence in the literature supporting the idea that lidocaine patches are effective in reducing postoperative pain and even reducing opioid consumption after surgery.[8,11,12] Our findings do not support a similar conclusion for patients undergoing rotator cuff repair, as no differences in pain levels or opioid consumption were found between the treatment and control groups. In fact, patients reported lower satisfaction with their pain control when given lidocaine patches.

Many of the studies reporting on the analgesic effects of lidocaine patches examine nonorthopedic procedures, and thus, results

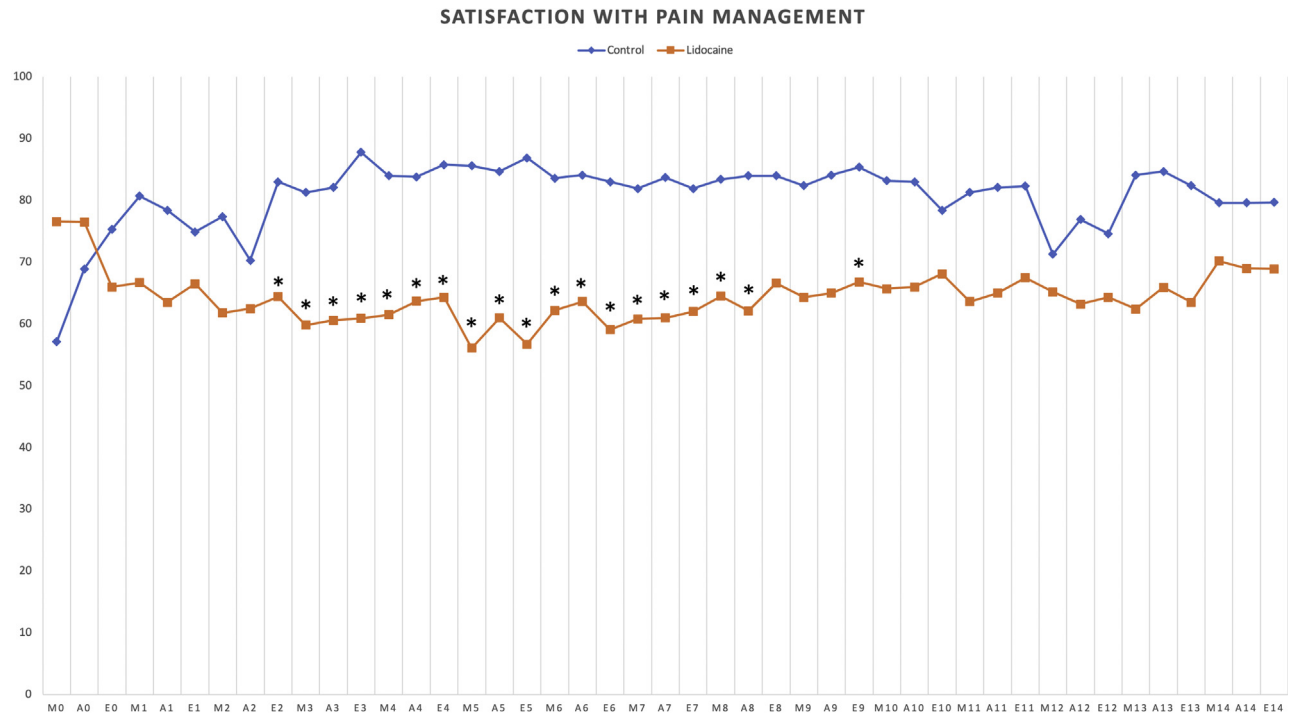

Figure 5 Satisfaction with pain management. *M*, morning; *A*, afternoon; *E*, evening. *Statistically significant at $P = .05$.

may not be transferrable to orthopedic surgery.[8,11,12] Kwon et al reported results on patients undergoing laparoscopic gynecologic surgery,[11] Habib et al on radical retropubic prostatectomy,[8] and Lee et al on laparoscopic appendectomy[12]; all three studies found improvements in reported pain levels with transdermal lidocaine patch use. Pathologies of the appendix, prostate, and gynecologic structures have referred pain due to inflammation or pressure due to growths. Thus, pain after these procedures was most likely due to superficial incisional pain, rather than at the surgical site. The pain of rotator cuff pathology is complex and multifactorial.[1] Incisional pain from portal sites is not likely the predominant source of pain after rotator cuff repair, which likely accounts for the lack of efficacy in this trial.

In the orthopedic literature, T5L patches have been investigated in rib fractures and arthroplasty. Prior studies have demonstrated the efficacy of lidocaine patches in the treatment of traumatic rib fractures, with Zink et al and Cheng et al reporting significant reductions in pain for rib fractures in trauma patients.[3,15] Sadigursky et al, who performed a trial evaluating the use of T5L patches after TKA, found that the T5L patches decreased narcotic consumption and postoperative pain.[14] Conversely, Khanna et al evaluated 53 patients after TKA and discovered that there was an increase in pain associated with T5L patch use.[10] The mechanism by which lidocaine patches alleviate pain in some musculoskeletal injuries, and not others, is likely secondary to the depth of the injured tissues and the ability of transdermal application to penetrate the soft tissues surrounding traumatized tissue. Ribs are relatively superficial structures with a thin layer of overlying skin and soft tissue, and in addition, some knee replacement discomfort may be associated with a significant amount of incisional pain. Arthroscopic rotator cuff repair has very little incisional pain secondary to the relatively small portal sites, and the structures repaired are deep to both skin and muscle, making penetration by a transdermal patch less likely.

Although pain due to superficial vs. deep structures is a possible reason for the lack of reported pain differences in our patient cohorts, it does not explain dissatisfaction with pain management. This may be explained by the non–placebo-controlled nature of our study. The perception of pain is complex and involves psychosocial components.[9] Our control group was blind to the existence of an experimental cohort. Thus, they had no placebo or any expectations for increased pain relief. Our experimental group may have had the expectation of better pain control with lidocaine patches. Meeting patient expectations for pain management is an important aspect of achieving patient satisfaction.[7] If the patches did not provide adequate pain control on par with patient expectations, that could have resulted in dissatisfaction with the care provided.

Finally, our findings may be due to the use of 4% over-the-counter transdermal lidocaine patches rather than 5% prescription patches. Although there are studies showing that these may be noninferior,[2] to our knowledge, this is the first investigation of 4% lidocaine patches in postoperative patients. This is a 20% reduction in dose, which may be more pronounced in studies of non-superficial sources of pain. We chose 4% because of its ease of application, over-the-counter availability, and generalizability of our findings because of these attributes.

A limitation of this study is the high attrition rate in this study. Only 66% (53) of enrolled patients were available for analysis. If attrition disproportionately accounted for patients who experienced low or high levels of pain, or had disproportionate levels of satisfaction, this may impact the final results. Such a significant dropout can lead to underpowered findings: our results showing transdermal lidocaine patches are ineffective in controlling postoperative pain may be incorrect. Another limitation is the experimental design. A provider treatment cross-over design was used rather than a completely randomized trial. This may lead to subtle differences in experimental vs. control groups that may not be detected by basic demographic characteristics. There was also lack of a placebo control in this study. Chronic pain patients were not explicitly excluded from the trial. We did not control for preoperative tear pattern. Although there was no statistical difference in tear pattern between groups, there was a wide range from partial thickness supraspinatus tears to massive rotator cuff tears with

multitendon involvement. When anatomically feasible, an attempt to make a tension-free double-row repair was made. However, two patients had collagen patch repairs, and several others had single-row repairs due to native anatomy. Finally, we did not assess the proper application of patches. We relied on written instructions provided to patients, but were unable to assess proper usage or application of patches at home.

Conclusion

Four-percent transdermal lidocaine patches are not effective in reducing postoperative pain or opioid consumption after arthroscopic rotator cuff repair. In addition, patients using the lidocaine patch experience less satisfaction with their pain management after rotator cuff surgery.

Disclaimers:

Funding: No funding was disclosed by the authors.
Conflicts of interest: M.D.P. reports general payment from Smith & Nephew, Inc. and Wright Medical Technologies, Inc. B.S.T. reports research support from DePuy, a Johnson & Johnson Company, research support from GID, and stock or stock options from Johnson & Johnson, is a paid consultant, paid presenter, or speaker in Mitek and DePuy, and is a paid consultant, paid presenter, or speaker in and reports research support from Pacira. F.P.T. is a board or committee member in AAOS, is a board or committee member in American Board of Orthopaedic Surgery, Inc., is a board or committee member in American Orthopaedic Society for Sports Medicine, reports stock or stock options from Franklin/Keystone Biosciences, LLC, reports stock or stock options from Trice Medical, Inc., is a paid consultant in Medical Device Business Services, Inc., and reports general payment from Smith & Nephew, Inc. and Medtronic USA, Inc.
The other authors, their immediate families, and any research foundation with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jseint.2021.09.006.

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