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Clinical Assessment of 5% Lidocaine Patches for Postoperative Analgesia: Efficacy, Effectiveness, and Safety

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Abstract

Pain management post-surgery is critical for effective recovery, yet conventional analgesics like opioids, nonsteroidal anti-inflammatory drugs (NSAIDs), and acetaminophen carry risks of side effects such as nausea and dependency. Transdermal lidocaine patches (LP) have emerged as an alternative, promising localized pain relief with minimal systemic effects. However, the efficacy of LP varies across surgical procedures. In arthroscopic rotator cuff repairs, LP did not significantly reduce pain or opioid consumption and was associated with lower patient satisfaction. Conversely, in laparoscopic cholecystectomy, LP reduced shoulder pain effectively but showed limited overall pain relief. Studies in thoracic and cardiac surgeries presented mixed results, with some showing initial pain reduction but no sustained benefits. In robotic cardiac surgery and sternotomy, LP significantly reduced pain and opioid use at various postoperative stages. A safety analysis across multiple studies confirmed LP's tolerability, with mild skin irritation as the most common adverse event and no serious systemic side effects reported. Despite its potential, the long-term benefits of LP, especially in reducing opioid dependence, remain under-researched. This review highlights the importance of further studies to optimize LP use and explore its comparative effectiveness against other pain management strategies, indicating a need for comprehensive evaluations to better delineate LP's role in postoperative pain management.

Keywords Lidocaine, Transdermal patches, Postoperative pain, Adverse events

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Introduction

Pain serves as a crucial component of the body's protective mechanisms, alerting it to potential harm and triggering protective reflexes. However, post-surgery pain can be particularly distressing and, if inadequately managed, may lead to complications such as prolonged hospital stays and hindered recovery [1, 2]. Conventional analgesics, including opioids, nonsteroidal anti-inflammatory drugs (NSAIDs), and acetaminophen, are commonly employed for postoperative pain management. Nevertheless, these medications often come with significant side effects, such as nausea, constipation, and risks of dependency, which can impede optimal recovery.

In recent years, there has been growing interest in alternative pain management strategies that minimize systemic side effects. Among these, transdermal patches, which deliver local anesthetic agents through the skin, have emerged as a promising option. These patches provide a targeted approach to pain relief, potentially reducing the need for systemic medications and their associated risks [3]. The efficacy and safety of local anesthetic patches, such as those containing lidocaine, are being increasingly explored as part of multimodal pain management strategies. Such therapy has several benefits, as well as some drawbacks, which are outlined in **(Table 1)**.

Table 1. Advantages and disadvantages of transdermal systems for pain management. Based on [4, 5]

Advantages	Disadvantages
convenience and compliance	possibility of skin irritation and/or allergic reactions
bypassing first-pass metabolism	variable absorption
bypassing the gastrointestinal effect	limited drug types (small molecular weight required)
do not pose a risk of disease transmission	not suitable for use in shock
low cost	adhesion issues
controlled release of the drug	
can be used when the oral form of the drug is not tolerated	

The risk of chronic opioid use increases after five days of postoperative therapy, making non-opioid alternatives like lidocaine crucial [6]. Lidocaine, known for its local anesthetic properties since the 1940s, not only provides pain relief but also exhibits anti-inflammatory effects, potentially offering prolonged benefits [7].

The transdermal drug delivery system

The transdermal drug delivery system (TDDS) allows controlled drug administration through the skin, offering an attractive alternative to oral delivery systems and subcutaneous injections. This method has been historically utilized in various forms, such as compresses, for therapeutic effects including pain relief. Today, a variety of drugs, including nicotine, estradiol, testosterone, and lidocaine, can be administered transdermally. Scopolamine was the first drug approved for transdermal delivery in the United States in 1979 to treat motion sickness [8].

Modern advancements in TDDS include the ability to deliver multiple drugs simultaneously and the use of adjuvants to enhance drug permeation by disrupting the skin barrier [9]. The advantages of TDDS include predictable and stable drug plasma concentrations, avoidance of first-pass metabolism, and reduced risk of infection and pain associated with needle use. Patches are also convenient for self-administration and can be removed as needed, allowing for extended drug release [10].

However, limitations include the inability to deliver large molecules, hydrophilic drugs, and certain biomolecules like peptides and RNA. Skin irritation is another potential issue [9, 11].

Transdermal patches comprise several components, such as a release liner, adhesive, polymer matrix or membrane, drug reservoir, and backing layer. Various types of patches, including single-layer, multi-layer, reservoir, and matrix patches, offer different drug release mechanisms. Drug penetration occurs through sweat glands, hair follicles, sebaceous glands, and the stratum corneum [5, 11].

TDDS has evolved through three generations, from simple low-weight, lipophilic drugs to more complex systems using chemical enhancers and microneedles to increase permeability and deliver macromolecules like proteins [10]. The effectiveness of TDDS depends on maintaining a concentration gradient, driving drug diffusion from the patch into the bloodstream [11].

This study aimed to comprehensively evaluate the efficacy and safety of lidocaine patches (LP) for postoperative pain management across a variety of surgical procedures. By analyzing data from multiple types of operations, the study aimed to determine the effectiveness of LP in reducing pain and opioid use, while assessing their impact on overall recovery. The study sought to provide a broad understanding of how LPs perform across different surgical settings and patient profiles, with the ultimate goal of informing best practices for pain management in postoperative care. The summary of reviewed studies is presented in **(Table 2)**.

Table 2. Characteristics of reviewed studies

Study	Study type	Operation type
Antony *et al*. 2021 [12]	A pilot randomized controlled trial	Cesarean section in obese women
Clark *et al*. 2018 [13]	A case report	Total knee arthroplasty
Fiorelli *et al*. 2019 [14]	A randomized, double-blind, placebo-controlled trial	Thoracotomy
Khanna *et al*. 2012 [15]	A prospective, single-center cohort trial	Total knee arthroplasty
Kim *et al*. 2021 [16]	A randomized, double-blind, prospective, parallel-group trial	Laparoscopic cholecystectomy

Kwon *et al*. 2012 [17]	A prospective, double-blind, placebo-controlled clinical trial	Gynecologic laparoscopic surgery
Lau *et al*. 2018 [18]	A pilot randomized controlled feasibility trial	Elective gynecological surgery with midline incisions
Lee *et al*. 2018 [19]	A randomized double-blind prospective study	Laparoscopic appendectomy
Lee *et al*. 2022 [20]	A prospective trial	Arthroscopic rotator cuff repair
Liu *et al*. 2019 [21]	A retrospective study	Thoracotomy and sternotomy
Park *et al*. 2020 [22]	A prospective, double-blind, placebo-controlled trial	Sternotomy
de Queiroz *et al*. 2018 [23]	A randomized placebo-controlled double-blind clinical trial	Cesarean section
Saber *et al*. 2009 [24]	A randomized, single-center, open-label trial	Laparoscopic ventral hernia repair
Vrooman *et al*. 2012 [25]	A randomized, placebo-controlled, double-blind trial	Robotic cardiac surgery

Efficacy and effectiveness for pain reduction

The effectiveness of LP for postoperative pain management was assessed across a range of surgical procedures, yielding a variety of outcomes. In the study by Lee *et al*. focusing on arthroscopic rotator cuff repair, the LP group initially reported higher overall use of "pain medications" like paracetamol and diclofenac at 2 weeks postoperatively, though "strong pain killers" usage remained similar between groups. By 6 weeks, this difference in medication use resolved, and cumulative morphine milligram equivalents were not significantly different between the LP and placebo groups. Despite similar pain levels and analgesic requirements, the LP group experienced lower satisfaction with pain management from postoperative day 2 through day 8, highlighting a possible disparity in perceived efficacy or side effects [20]. The issue of pain management in orthopedic surgeries is further illustrated by a case report of a 71-year-old woman with rheumatoid arthritis who underwent left total knee arthroplasty. Despite receiving preoperative acetaminophen and an adductor canal nerve block with bupivacaine, she experienced severe pain, scoring 8/10, which persisted despite the administration of hydromorphone and gabapentin. On postoperative day 4, a lidocaine 5% patch was applied circumferentially around her thigh, leading to a significant reduction in pain to 2/10 within 2 hours. This improvement allowed her to participate in physical therapy and facilitated her discharge the following day [13]. Contrasting results were noted in a study by Khanna *et al*. which also involved patients undergoing total knee arthroplasty. It revealed no statistical difference in pain relief on days 1, 5, 7, 9, and 11 post-surgery, although statistically lower pain scores were observed in the control group on day 3. Surprisingly, 94% of the patients receiving LP were satisfied with the treatment, emphasizing other benefits of transdermal therapy beyond pain relief, such as convenience [15].

In laparoscopic procedures, Lee *et al*. and Kim *et al*. provided contrasting results. Lee *et al*. observed that while LP use led to a significant reduction in pethidine consumption, overall pain scores and general analgesic needs did not differ markedly from those of the placebo group. The study noted no significant impact on the visual analog scale (VAS) scores at various surgical sites, indicating that while LP may reduce some aspects of pain, its overall impact on pain management was modest [19]. In contrast, Kim *et al*. found that LP was particularly effective in reducing shoulder pain, a common issue following laparoscopic cholecystectomy. The LP group exhibited significantly lower pain scores at 24- and 48-hours post-surgery compared to the placebo group, although the overall efficacy in pain reduction was comparable to that of the placebo in other areas [16]. This suggests that LP may have specific benefits for localized pain management. Finally, a study by Saber *et al*. examined patients following laparoscopic ventral hernia repair and found that patients receiving LP had significantly lower pain scores at discharge compared to the control group. Two weeks after surgery, the LP group still reported lower pain scores, but this difference was not statistically significant. By two months post-surgery, pain scores for both groups were nearly identical. Additionally, patients receiving LP had a shorter hospital stay, though this difference did not reach statistical significance [24].

Liu *et al*. evaluated LP in patients undergoing cardiothoracic procedures. This study revealed that LP did not significantly alter pain outcomes, opioid use, or hospital stay duration compared to placebo [21]. In contrast, Fiorelli *et al*. who examined patients following thoracotomy, found that LP significantly reduced VAS scores for postoperative wound pain 6-72 hours at rest and after coughing, with improvements in respiratory function and decreased analgesic drugs administration frequency. However, the initial significant differences in pain scores 6- and 72-hours post-surgery did not persist after adjusting for multiple comparisons [14]. Furthermore, Vrooman and Park with their coworkers assessed LP in robotic cardiac surgery and sternotomy operations, respectively. The first study found no significant differences between the LP and placebo groups across several measures, including pain disability index, VAS

pain scores, and opioid consumption. Additionally, LP had no impact on global patient evaluation domains such as pain, treatment efficacy, or patient satisfaction [25]. On the contrary, Park *et al*. reported substantial reductions in pain intensity with LP, ranging from 66% to 68% compared to placebo, and noted a significant decrease in opioid consumption in the first 48 hours post-surgery. This suggests that LP may offer meaningful benefits in managing acute postoperative pain and reducing opioid dependency in specific settings [22].

Another two studies examined the effects of LP on postoperative pain management in patients undergoing gynecological surgeries. Kwon *et al*. found that LP significantly reduced postoperative wound pain at 1 and 6 hours after surgery, as well as pain at rest at 1 hour, compared to the control group. However, no significant differences were observed in pain during ambulation, shoulder pain, or the most severe pain site, and analgesic requirements were similar between groups [17]. Lau *et al*. reported that the LP group had significantly lower pain scores at rest 24 hours post-surgery but not during movement. Both groups experienced a time-dependent decrease in pain intensity, but the overall reduction in pain and cumulative morphine consumption was not significantly different between the lidocaine and placebo groups. Additionally, improvements in respiratory function and postoperative length of stay were minimal and comparable between the groups [18].

Finally, the LP's efficacy was explored in cesarean sections. De Queiroz *et al*. observed significantly lower pain scores for postoperative pain with LP at 6, 12, 24, and 36 hours compared to placebo. Despite these findings, the overall tramadol consumption and quality of recovery measures did not differ significantly between groups, suggesting that while LP may improve early pain control, it does not significantly impact long-term opioid use or recovery outcomes [23]. Antony *et al*. reported similar findings, with no significant differences in opioid use, pain scores, or patient satisfaction between LP and placebo groups among obese women. Pain scores in the first 24 hours post-cesarean were comparable between the groups, and LP-related toxicities were similar to those observed with placebo, indicating a lack of substantial difference in effectiveness or safety [12].

In summary, these studies indicate that LP can be an effective tool for managing postoperative pain and reducing opioid use across various surgical procedures. However, its effectiveness appears to vary depending on the type of surgery and patient characteristics. While LP demonstrates considerable benefits in specific contexts, such as shoulder pain management and early postoperative pain relief, its overall impact on long-term pain outcomes and opioid consumption remains mixed. Further research is needed to refine the use of LP in different surgical settings and to compare its efficacy with other pain management options.

Safety of the lidocaine patch

A comprehensive safety analysis was conducted across nine studies to evaluate the safety profile of the LP for pain management. These studies collectively provided data on adverse events (AEs) related to LP use, documenting the incidence of side effects and any potential complications. Overall, LP was found to be well-tolerated across various surgical procedures, with no serious systemic side effects reported. Specifically, none of the patients in the studies reported nausea, vomiting, erythema, rash, contact dermatitis, hypotension, bradycardia, cardiovascular instability, headache, or dizziness [19]. In a similar vein, Fiorelli *et al*. found no significant differences in operative time, length of chest drainage, length of hospital stays, or postoperative complications between the LP and placebo groups [14]. Kim *et al*. also reported that while nausea developed in 24 patients, distributed equally between LP and placebo groups, no other complications related to LP use were observed [16]. For specific AEs, Kwon *et al*. found no wound problems, contact dermatitis, or systemic side effects [17], and de Queiroz *et al*. noted that headache, nausea, or dizziness were not significantly different between LP and placebo groups [23]. Another four studies noted no AEs attributable to the patches during the trial [15, 18, 24, 25]. Park *et al*. similarly reported no significant differences in the incidence of sleep disturbance, opioid use, or patch-related outcomes like nausea, vomiting, or pruritus between groups [22]. Collectively, these studies indicate that LP is generally safe with minimal adverse effects, predominantly localized to the application site, and not significantly different from those experienced with placebo.

Results and Discussion

This narrative review evaluates the existing literature on the efficacy, effectiveness, and safety of transdermal LP for postoperative pain management. Although LPs are increasingly considered in multimodal pain management strategies, there remains limited systematic investigation with sufficient evidence to draw definitive conclusions.

Among the reviewed studies, a diverse range of methodologies was employed, including prospective trials, retrospective studies, randomized controlled trials (RCTs), and one case report. Notably, while some studies demonstrate promising outcomes, others exhibit significant methodological limitations. For example, several trials reported mixed results due to small sample sizes or lack of control groups, which impairs the ability to make robust conclusions. In particular, one RCT had a relatively small sample size (n = 28) [18].

A search of clinical trial registries revealed additional studies on LP that remain unpublished. These trials, which include both completed studies and those terminated early, raise concerns about potential publication bias. The absence of published results from these studies may suggest a tendency to report positive outcomes selectively, potentially obscuring null or negative findings. This raises questions about the overall reliability of the reported benefits of LP.

In terms of efficacy, the studies reviewed show a varied impact of LP on postoperative pain. For instance, Lee *et al*. found that LP users initially required more pain medications, though, by six weeks, differences in medication use between LP and placebo groups were not statistically significant [20]. This suggests that while LP may affect initial pain management satisfaction, its long-term efficacy remains unclear.

For specific types of surgery, such as laparoscopic procedures, results were mixed. Lee, Kim, and Saber with their coworkers provided contrasting outcomes, with LP showing significant benefits in localized pain relief in some cases but not in others [16, 19, 24]. Similarly, in thoracic and cardiac surgeries, the effectiveness of LP varied. Liu *et al*. found no significant advantages of LP over placebo [21], while Park *et al*. reported a substantial reduction in pain intensity and opioid consumption [22]. Interesting findings were noted by Khanna *et al*. who revealed that despite no statistical differences in pain relief, patients were satisfied with treatment with LP, which underscores additional advantages of transdermal therapy [15].

The safety profile of LP, as indicated by the reviewed studies, appears generally favorable. Profile of the AEs incidence was similar between experimental and control groups, with no serious systemic effects reported. Moreover, several studies have not noted any AEs associated with LP use.

This review highlights several limitations in the available literature, including the quality of the studies and the potential for publication bias. The inclusion of only English language studies further restricts the breadth of the review. A more comprehensive analysis, including direct statistical comparisons between LP and placebo in terms of efficacy, safety, and quality of life, would provide a clearer understanding of LP's role in postoperative pain management.

Conclusion

Overall, while LP shows potential benefits for certain types of postoperative pain, its overall efficacy and impact on long-term pain management remain inconclusive. Further research with larger, methodologically sound trials is needed to establish more definitive conclusions about the role of LP in postoperative pain management.

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