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ORIGINAL ARTICLE

# The prescription of lidocaine patches in osteoarthritis—a complete audit cycle

Rosie Mc Colgan[1] · David M. Dalton[1] · Hugh P. O'Sullivan[1] · James A. Sproule[1]

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## Abstract

**Objectives** Nationally, 5% of the population have been prescribed topical lidocaine patches (TLPs). These patches cost €77–230 per month. The only licensed indication for TLP is post-herpetic neuralgia (PHN). It has not proven to be effective for any other indication including musculoskeletal and post-surgical pain. It is estimated that only 5–10% of patients on TLP have PHN. The aim of this study was to audit the number of inpatients currently prescribed TLP—appropriately and inappropriately—and to examine the prescribing patterns.

**Methods** The acute inpatient population was audited in August 2017 to determine TLP prevalence. Demographics, indication, prescriber grade, and whether TLP was commenced during the current admission were recorded. Education was given surrounding indications and licensed usage of TLP. The acute inpatient population was subsequently re-audited in February 2018.

**Results** There were 304 patients included in the initial study and 300 in the repeat study. The most common indication was musculoskeletal pain in each study, 75 and 77.78%, respectively. The number of inpatients on TLP fell from 17.1% ($n = 52$) to 6% ($n = 18$) after the intervention. The potential savings between the study periods are therefore €31,418–93,840 in total and €23,100–69,000 in musculoskeletal patients.

**Conclusion** A large proportion of inpatients are inappropriately prescribed TLP predominantly for musculoskeletal pain, resulting in substantial avoidable cost to the hospital. Education of prescribers and implementation of policies is required to limit inappropriate prescribing.

**Keywords** Audit · Health economics · Lidocaine patch · Osteoarthritis · Prescribing patterns

## Introduction

The prevalence of osteoarthritis (OA) in people over the age of 50 in Ireland is 12.9% [1]. OA may initially be managed non-operatively [2]. International guidelines recommend that patients should be referred for consideration for total joint arthroplasty (TJA) prior to the establishment of functional impairment, or when pain is not adequately controlled by analgesia [2, 3].

TJA has been clinically proven to be a safe and effective treatment for arthritis of the knee and hip [4, 5]. While joint arthroplasty has good outcomes and is a cost-effective measure in the management of OA, there are significant complications that may occur with any joint replacement procedure. Non-operative alternatives (weight loss, exercise, analgesia, aids) should be discussed with any patient considering TJA [6–8].

The number of patients eligible for TJA is increasing, with a subsequent increasing burden on healthcare services worldwide. This increase in demand is secondary to an aging population, improvements in surgical and anesthetic techniques, and the availability of higher quality devices [9, 10]. Resources should be allocated between operative and non-operative interventions that are both clinically effective and cost-efficient. Inefficiencies in the system should be minimized in order to optimize patient care.

Topical lidocaine patches (TLPs) (Lidoderm™ or Versatis™) are licensed in Ireland for the symptomatic relief of post-herpetic neuralgia (PHN). Therapy with TLP costs €77–231 per patient per month depending on the number of patches applied. Current expenditure is in excess of €30

✉ Rosie Mc Colgan
mccolgar@tcd.ie

[1] Department Orthopaedics, Tallaght University Hospital, Dublin 24, Ireland

million per annum nationally [11]. Recent changes in the national health policy have limited the reimbursement of TLP on the Drug Payment Scheme for the indication of PHN and in exceptional circumstances. This move generated debate in the houses of parliament and on all forms of mainstream media [12]. This legislation affects only outpatient prescriptions, and there is currently no limitation on inpatient prescribing.

The primary aim of this study was to audit the number of inpatients in a University Teaching Hospital receiving TLP therapy and to examine prescribing patterns surrounding this. The secondary aim of the study was to determine whether inappropriate prescribing practices could be reduced by education sessions delivered by peers.

## Methods

The acute inpatient population was audited in August 2017 to determine TLP prevalence. Gender, age, and the admitting team were recorded for those on TLP. Indication, prescriber grade, and date prescription was commenced were recorded. Any prescription which was commenced on the admission date was reconciled with preadmission medications to determine whether it was newly prescribed or not. Any prescription dated after admission was considered a new prescription.

Education was given surrounding indications and licensed usage of TLP in the inpatient and outpatient setting to non-consultant hospital doctors (NCHDs). The education was given at two separate intervals by 2 of the co-authors in the form of didactic lectures at weekly intern teaching sessions.

The acute inpatient population was subsequently re-audited in February 2018 to determine TLP prevalence and the characteristics listed above were once again recorded. Both aforementioned teaching sessions were delivered in the interval between the two data collection points. The introduction of the new policy on outpatient prescribing and subsequent media attention also occurred in the period between the two data collection points.

No changes to the patients' prescriptions were offered directly by the study team, and the study team did not interfere or direct individual patient care in any manner. Ethical approval was sought and obtained for this study. A significance level of 0.05 was used for all statistical analyses, which were performed using Minitab 17 Version 4.

## Results

There were 304 patients included in the initial survey. Fifty-two patients (17.1% CI 0.13,0.21) had been prescribed TLP (Fig. 1a). The median age of patients on TLP was 72.5 years. There were 28 females and 24 males on TLP—38 medical and 14 surgical patients. Musculoskeletal pain (75%, $n = 39$) was the most common indication (Fig. 2). Post-operative pain (5.7%, $n = 3$), chest pain (3.8%, $n = 2$), and abdominal pain (1.92%, $n = 1$) were also documented indications. The indication was undocumented in 13.46% ($n = 7$) of cases. No patients were prescribed TLP for PHN. Of patients on TLP therapy, 53.84% ($n = 28$) commenced TLP during their current inpatient stay. The most frequent prescribers were registrars (28.57%, $n = 8$) followed by interns (21.42%, $n = 6$) (Fig. 3). The prescribing doctor grade was unknown in 28.57% ($n = 8$) of cases due to illegible signature on the drug Kardex and no record of medical council number or documentation in the medical notes. Based on current levels of usage, the cost to the hospital is €48,050–143,520 per annum. The annual expenditure on TLP for MSK pain is €36,036–€108,108.

In the repeat survey, there were 300 patients included. Eighteen patients (6% CI 0.36,0.93) had been prescribed TLP (Fig. 1b). The median age of patients on TLP was 72.5 years. There were 8 females and 10 males on therapy—11 medical and 7 surgical patients. Musculoskeletal pain (77.78%, $n = 14$) was the most common indication. Chest pain (5.56%, $n = 1$) was also a documented indication. None of these patients had a history of PHN. During their current inpatient stay, 61.11% ($n = 11$) commenced therapy. The most frequent prescribers were SHOs (54.54% $n = 6$) followed by interns (21.42%, $n = 2$). The prescriber grade could not be identified in 27.27% ($n = 3$) of cases. Based on these levels of usage, the cost to the hospital is €16,632–49,680 per annum. The annual expenditure on TLP for MSK pain is €12,936–€38,808.

The number of inpatients on TLP fell from 17.1 to 6% after the intervention which was a statistically significant difference ($p = 0$, paired Student $t$ test). The proportion of patients starting TLP as an inpatient rose from 53.84 to 61.11%; however, this was not statistically significant ($p = 0.786$, paired Student $t$ test).

The potential savings between the study periods are therefore €31,418–93,840 in total and €23,100–€69,000 in MSK patients.

## Discussion

The discrepancy in prescribing behavior between doctors is a cause for concern, and changing this is challenging. There are many factors determining prescribing patterns. High prescribers are less cost aware and less likely to adhere to guidelines [13]. While clinicians do not feel that the pharmaceutical industry exerts an influence on their prescribing, the patient population is more skeptical [14, 15]. Doctors appear to be more compliant with patient demands than government policy. The latter is often perceived as an infringement on doctors' autonomy, and some feel that the focus is more on cost-saving measures than on patients best interests [16, 17]. There have

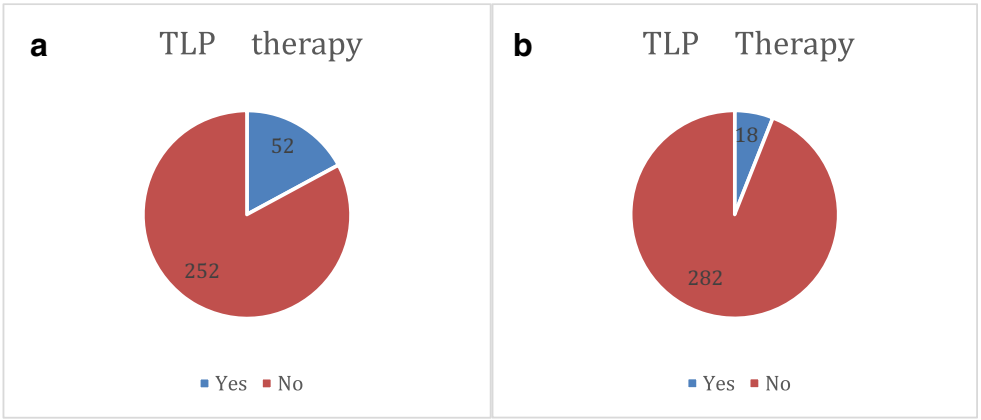


**Fig. 1** **a** Number of patients on TLP therapy prior to intervention. **b** Number of patients on TLP after intervention

been attempts predominantly in the antibiotic domain to try and change prescribing behavior in doctors [18–20]. One method of influencing prescribing behavior that has proven successful is electronic prescribing. One study performed in the UK demonstrated that the use of prompts to select the most cost-efficient drugs did indeed influence prescribing behavior [21]. In this particular study, the changes involved the substitution of generic drugs for the more expensive branded products which did not impact physician autonomy. In the present study, an intervention in the form of peer-delivered teaching was delivered, and the outcome measure was the number of inpatient prescriptions commenced by interns. The number of prescriptions initiated by interns fell from 21.42 to 18.18% between the two data collection points. This was not statistically significant. The education given about TLP indications was administered solely to interns. Interns frequently prescribe medications based on senior advice; therefore, these results should be interpreted with caution. It does not necessarily reflect the impact of peer-delivered teaching sessions on prescribing behavior as such but may imply that teaching needs to be administered to all members of the team to have a significant impact.

In the current study, 53.84–61.11% of TLP therapy was initiated as an inpatient. This figure only encompasses patients started on TLP during their current inpatient stay. The number of patients commencing TLP in hospital may be higher as we did not take into account any prescriptions commenced on previous hospital admissions. The proportion of patients who commenced therapy as an inpatient rose in the interval between our data collection points, despite the overall proportion of patients on therapy decreasing. This may reflect the changes on outpatient prescribing that were brought into effect in the interim. Patients commenced on TLP as an inpatient will be unable to avail of it on the current DPS upon discharge. The practice of commencing TLP in patients who will be unable to access them in the community causes unnecessary distress to patients. It may result in pain relapse on discharge if the patches were an effective measure of pain control. The pattern of drug regime alterations on hospital admission and discharge is consistent with literature. More than 60% of patients have changes made to their chronic drug regime while they are in hospital [22]. This disruption can result in administration errors and reduce patient compliance. In a Norwegian study that included 105 patients, the authors found an average

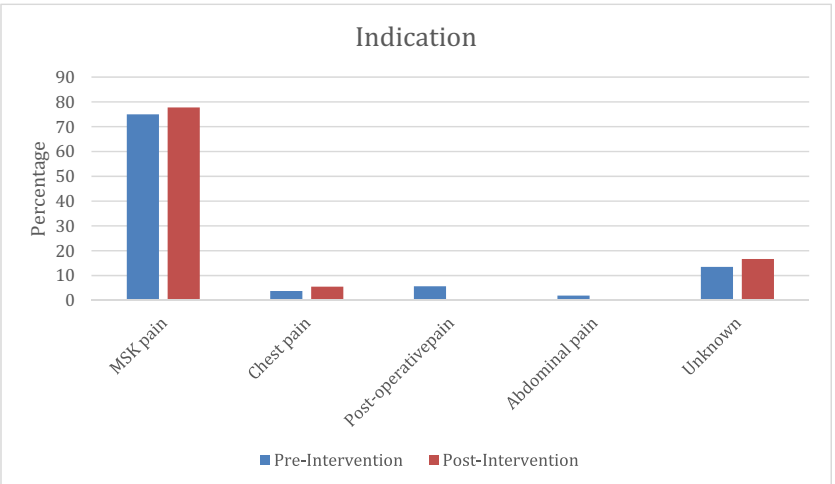


**Fig. 2** Indication for commencing TLP therapy

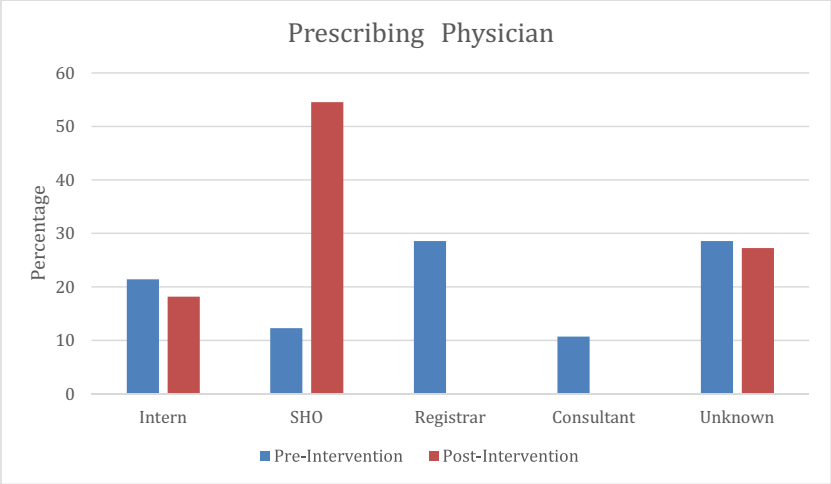


**Fig. 3** Prescribing physician

increase from 5.6 medications on admission to 7.6 medications on discharge. Patients had an average of 4.4 medication during their inpatient stay, a further 3.4 medication changes in the 4–5 months post-discharge [23].

The most common indication for TLP therapy was MSK pain, predominantly OA. OA is a common chronic condition that exerts a considerable burden on the health service. A coordinated multimodal management pathway is necessary for efficient delivery of care. The NICE guidelines recommend exercise and weight loss as the first-line treatment of OA [2]. Paracetamol and topical therapies such as diclofenac and capsaicin are first-line pharmacological therapy. Oral NSAIDs, cyclooxygenase 2 (COX-2) inhibitors, and opioids should be considered if these measures fail. Intra-articular injections may be used as an adjuvant therapy. Patients should be referred early for joint replacement surgery before disease progression. Patients with joint symptoms that have a substantial impact on their quality of life should be referred for joint replacement surgery. Three potential targets for pain relief in OA—synovitis, bony lesions, and central sensitization—are addressed by these guidelines.

TLP is an adhesive hydrogel plaster that exerts its analgesic effect peripherally by blocking neuronal sodium channels [24, 25]. This impairs the conduction of signals associated with the perception of peripheral pain. The available market patches diffuse lidocaine continuously across the skin producing a local effect. The hydrogel layer of the plaster provides a mechanical effect on pain. Burch et al. [26] reported that TLP improves pain, stiffness, and functional outcomes when used as adjuvant therapy in patients with OA of the knee. This prospective, open-label trial had a short duration of 2 weeks and was funded by Endo Pharmaceuticals Inc., who produces Lidoderm. Another study by Gammaitoni et al. [27] found that patients with OA of the knee had reduced neuropathic pain scores after 2 weeks of TLP. Patients in this study were only followed up for a short duration of 2 weeks, and this trial was once again funded by Endo Pharmaceuticals Inc. The American Academy of Orthopaedics (AAOS) recommend self-management programs, physical activity, weight loss, NSAIDs (oral or topical), and tramadol in the management of symptomatic OA of the knee [28]. They do not recommend the use of pain patches. Osteoarthritis Research Society International (OARSI) recommend paracetamol, NSAIDs, topical NSAIDs, and topical capsaicin in the pharmacological management of hip and knee OA [3]. TLP therapy does not feature in their recommendations. The European Society for Clinical and Economic Aspects of Osteoporosis and Osteoarthritis (ESCEO) recommend paracetamol, topical NSAIDs, oral NSAIDs, and finally tramadol in their treatment algorithm [29]. TLP therapy does not feature in their recommendations.

TLP is currently not recommended by international guidelines for the treatment of OA. While they may be of benefit in some patients or a short-term treatment, current levels of usage and expenditure are excessive. Resources should be directed towards earlier surgical intervention in patients with OA and research should be directed towards effective pain management strategies in patients unsuitable for surgical intervention.

## Conclusion

The efficacy of TLP in treating the pain associated with OA is unknown. An independent randomized control trial or prospective cohort trial is needed to determine the efficacy of TLP. Evidenced-based guidelines need to be produced by invested bodies and introduced across all sectors of the healthcare to prevent inconsistencies in patient management between medical professionals, between inpatient and outpatient settings and between government bodies and medical professionals. Educating doctors on current guidelines and media attention to the matter can change doctors' behavior and reduce inappropriate or unlicensed prescription but not altogether abolish it. Medical professionals should consider

the opportunity cost of unproven treatments before employing them as it may prevent other patients availing of more effective treatments.

## Compliance with ethical standards

**Conflict of interest** The authors declare that they have no conflict of interest.

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