Switching Topical Diclofenac from Higher to Lower Strength: Financial and Clinical Evaluation

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ABSTRACT

Background: In February 2020, the Fraser Health Authority in British Columbia introduced an automatic therapeutic interchange policy, whereby orders for any strength of topical diclofenac would be automatically interchanged to the commercially available diclofenac 2.32% gel for twice-daily administration. The new policy was intended mainly as a cost-saving measure but had the potential for clinical impacts that needed to be considered.

Objectives: To evaluate the financial and clinical impact of the automatic therapeutic interchange policy for topical diclofenac.

Methods: A financial evaluation and a clinical evaluation were conducted. Expenditures for topical diclofenac before and after implementation of the automatic therapeutic interchange policy were compared. To obtain information about the clinical impact of the interchange, a retrospective chart review was conducted at long-term care sites. The primary outcome was a composite of 7 components that could indicate worsening of pain in 3 prespecified scenarios.

Results: The financial evaluation showed that the interchange could potentially save the health authority more than $200 000 over 12 months. The clinical evaluation showed that 25%–48% of patients met the primary outcome of worsening pain (analyzed according to 3 different scenarios) after the switch to lower-strength diclofenac, with increases in use of as-needed topical diclofenac and other analgesics being the main indicators of worsening pain.

Conclusions: An automatic therapeutic interchange policy that switched orders for higher strengths of diclofenac to the 2.32% concentration resulted in large financial savings and, in most cases (52%–75% of patients), did not appear to affect pain control. Prospective studies comparing the clinical impact of higher- and lower-strength topical diclofenac products are warranted.

Keywords: topical, diclofenac, pain, therapeutic interchange, dose–response relationship

RÉSUMÉ

Contexte : En février 2020, la Fraser Health Authority en Colombie-Britannique a introduit une politique d'échange thérapeutique automatique, selon laquelle les commandes de diclofénac topique (n'importe quelle concentration) seraient automatiquement échangées contre du diclofénac à 2,32 % (formule en gel) disponible dans le commerce pour une administration deux fois par jour. La nouvelle politique visait principalement à réduire les coûts, mais pouvait avoir une incidence clinique, qui devait être prise en compte.

Objectifs : Évaluer l'impact financier et clinique de la politique d'échange thérapeutique automatique pour le diclofénac topique.

Méthodes : Une évaluation financière et une évaluation clinique ont été réalisées. Les dépenses liées au diclofénac topique avant et après la mise en œuvre de la politique d'échange thérapeutique automatique ont été comparées. Pour obtenir des informations sur l'incidence clinique de l'échange, un examen rétrospectif des dossiers a été réalisé dans les sites de soins de longue durée. Le résultat principal était un composite de 7 éléments pouvant indiquer une aggravation de la douleur dans 3 scénarios prédéfinis.

Résultats : L'évaluation financière a montré que l'échange pourrait potentiellement permettre à l'autorité sanitaire d'économiser plus de 200 000 $ sur 12 mois. L'évaluation clinique a quant à elle démontré que 25 à 48 % des patients ont atteint le principal résultat d'aggravation de la douleur (analysé selon 3 scénarios différents) après le passage au diclofénac à plus faible concentration. L'augmentation de l'utilisation au besoin de diclofénac topique et d'autres analgésiques constituait le principal indicateur d'aggravation de la douleur.

Conclusions : Une politique d'échange thérapeutique automatique qui remplaçait les ordonnances de concentrations plus élevées de diclofénac par une concentration de 2,32 % a permis de réaliser d'importantes économies financières et, dans la plupart des cas (52 à 75 % des patients), cet échange ne semble pas avoir eu d'effet sur le contrôle de la douleur. Des études prospectives comparant l'incidence clinique des produits topiques à base de diclofénac à concentration plus élevée et plus faible sont justifiées.

Mots-clés : médicament topique, diclofénac, douleur, échange thérapeutique, relation dose-réponse

INTRODUCTION

Topical diclofenac is a nonsteroidal anti-inflammatory drug used to treat acute or chronic localized musculoskeletal pain.[1-3] In Canada, 3 topical diclofenac products are commercially available for the treatment of muscle or joint pain: 1.5% diclofenac topical solution, 1.16% diclofenac gel, and 2.32% diclofenac gel.[1-4] Higher-strength topical diclofenac products, such as 5% and 10% gels, can be compounded

(e.g., in a Phlogel base) at pharmacies; these formulations are also used for the treatment of muscle and joint pain. Typical regimens for topical diclofenac vary according to product strength: the 2.32% product is applied twice daily, whereas the 1.5% and 1.16% products are applied 3 or 4 times a day.[1-3]

The Pharmacy Department of the Fraser Health Authority in British Columbia provides services to 12 acute care hospitals (with a total of 1447 beds), and 16 long-term care facilities (with a total of 2192 beds). On February 5, 2020, the Fraser Health Authority introduced an automatic therapeutic interchange (ATI) policy, whereby orders for any strength of topical diclofenac would be automatically interchanged to the commercially available diclofenac 2.32% gel for twice-daily administration. This interchange policy was introduced mainly as a cost-saving mechanism. At that time, the cost of purchasing compounded diclofenac 5% and 10% gel was $21.50 and $24.50, respectively, per 25 g. By comparison, the cost to purchase commercially available 2.32% topical gel was much less, at $6.42 per 30-g tube.

A systematic search of the literature performed shortly before the ATI policy was implemented did not uncover any evidence directly comparing different strengths of topical diclofenac; as such, it was unknown whether higher strengths were associated with greater efficacy than lower strengths.[5] We updated the search to June 2022 and again found no relevant literature comparing the efficacy of different strengths of topical diclofenac. Given the absence of evidence, it was considered reasonable to implement ATI to the 2.32% commercially available strength of topical diclofenac; this product was preferred, given its twice-daily regimen. As with any therapeutic interchange policy in the health authority, prescribers could indicate "no substitution" if there was an identified clinical need for a specific strength of topical diclofenac other than 2.32%.

Following implementation of the ATI policy, it was pertinent to determine its financial and clinical impacts. In particular, there was a need to know whether patients who were switched from a higher-strength diclofenac product to a 2.32% product experienced any uncontrolled pain. Hence, financial and clinical evaluations using a retrospective chart review were undertaken.

METHODS

The Fraser Health Research Ethics Board confirmed that no ethics approval was required. This review was granted the exemption because it was deemed a quality improvement evaluation.

Financial Evaluation

The total expenditure for compounded topical diclofenac 10% (25-g tube), compounded topical diclofenac 5% (25-g tube), commercially available topical diclofenac 2.32% (30-g tube), and commercially available diclofenac 1.16% (30-g tube) was determined for the year before and the year after implementation of the ATI policy. The following specific dates were selected, to reflect full fiscal periods: January 11, 2019, to January 9, 2020 (before ATI); and February 7, 2020, to February 4, 2021 (after ATI).

To determine total expenditure, the number of units of each type issued to the ward, either on a patient-specific basis or as ward stock, was collected and multiplied by the respective cost to purchase each unit. The difference in expenditure between the 2 periods was calculated.

Knowing that uptake of the ATI policy would take some time after implementation, we also identified the time point at which the ATI policy appeared to be fully functional (i.e., the tipping point). The ATI policy was considered to be fully functional when the 2.32% gel was the dominant topical diclofenac product being used, and the number of units of 2.32% gel issued by pharmacy appeared to plateau. The expenditure from the tipping point onward was extrapolated to a full fiscal year (i.e., 13 fiscal periods, 28 days per fiscal period). The difference in expenditure for the year before implementation of the ATI policy and the extrapolated year was also calculated.

Retrospective Chart Review

Study Design

The retrospective chart review was performed across 4 long-term care facilities in the Fraser Health Authority: Langley Memorial Hospital, Ridge Meadows Hospital, Queen's Park Care Centre, and CareLife Fleetwood. Patients were included if the pharmacy dispensary's computer system showed a same-day switch in drug entries from 5% or 10% topical diclofenac to 2.32% topical diclofenac between February 1 and November 30, 2020. Patients were excluded if their medication administration record showed a gap of 1 or more days between discontinuation of 5% or 10% topical diclofenac and initiation of 2.32% topical diclofenac. The aim of the chart review was to gather information on any indicators of a decline in patient's pain control when they were switched from higher-strength (5% or 10%) topical diclofenac to lower-strength (2.32%) topical diclofenac following implementation of the ATI policy.

Outcomes

The primary outcome of this study was the proportion of patients with a composite outcome consisting of 1 or more of the following elements, after the switch to 2.32% topical diclofenac:

(a) switch back to a higher strength of topical diclofenac
(b) increase in frequency of diclofenac 2.32% administration
(c) increase of 30% or more in the number of times diclofenac was administered on a PRN order
(d) ordering of 1 or more new analgesics, other than topical diclofenac (acetylsalicylic acid 80 mg or 81 mg was

not considered to represent an analgesic order, because these regimens are typically used for cardioprotective effects, rather than pain management; adjuvant therapy such as gabapentin was not included)

(e) increased dose or frequency of an existing regularly scheduled analgesic, other than topical diclofenac

(f) increase of 30% or more in the total quantity (mg) of PRN analgesic administered, other than topical diclofenac

(g) existing analgesic switched from PRN administration to regularly scheduled administration

The primary outcome served as an indicator of worsening pain control resulting from the switch to lower-strength diclofenac. The secondary outcomes were the total number and proportion of patients with each component of the primary outcome.

Data Variables

Data variables collected from the charts included patients' age, sex, height, and weight. Death, initiation of the active dying protocol, onset of new painful conditions (e.g., tooth extraction or a fall), or change in pain condition during the 1-month period after the ATI switch were also collected. Variables pertaining to topical diclofenac and other analgesics were the application site and indication, order date, discontinuation date, strength, frequency, administration schedule (regularly scheduled versus PRN), and frequency of administration of a PRN order. The timeframes for variables related to medications was 1 month before and 1 month after the switch in product strength. For patients lost to follow-up (i.e., those who died, were discharged, or were transferred to a different facility), only data up to the last day of follow-up were used. If medication administration records were unavailable, pharmacy dispensary data were used, if possible.

Patient records at the 4 long-term care facilities are paper-based. Therefore, data were collected using a "2-tier" system, whereby the physical (paper) charts were reviewed first, with electronic medical records used as a supplement. For pilot testing of the data collection form and to help validate data extraction, the data extraction was performed separately by 3 investigators (E.S.Y.A., A.K.D., N.K.) at CareLife Fleetwood. Discrepancies were discussed among the 3 investigators and resolved. Thereafter, data extraction for the remaining 3 sites was performed in duplicate by 2 of the investigators (A.K.D. and N.K.), who discussed, agreed upon, and resolved any discrepancies or ambiguities in the data.

Data Analysis

End points were analyzed using descriptive statistics. The primary composite end point was analyzed according to 3 prespecified scenarios. The first scenario was based solely on medication orders and medication administration records. The second scenario took into account explicitly documented reasons for medication administration and orders. For scenario 2, patients who met the primary composite end point under scenario 1 were recategorized as not meeting the composite end point if there was explicit documentation that the reason for meeting the composite end point was a medical condition unrelated to the one being treated by topical diclofenac.

For scenario 3, investigators took into account the patient's entire clinical presentation and all medical conditions to determine whether the primary composite end point was met because of implementation of the ATI policy. Medication orders that were changed on the same day that diclofenac strength was reduced were deemed to be unrelated to the ATI policy, because there would not have been enough time to see any effect of the change in diclofenac strength. Furthermore, recent history of increased analgesic use, before the switch in diclofenac strength, was interpreted as an indication of existing unmanaged pain, and any further medication changes after the diclofenac switch were considered to be unrelated to the ATI policy. Changes to medication orders during a hospital admission for a new medical condition, initiation of the active dying protocol, or medication changes on the day of a patient's death were also judged to be unrelated to the diclofenac switch.

Secondary end points were analyzed solely on the basis of medication orders and medication administration records. The 30% threshold for increase in PRN administration of analgesics was determined arbitrarily, as a brief literature search did not identify any generally accepted threshold. Patients with missing or incomplete medication administration records for PRN use were excluded from the analysis of the primary outcome (i.e., not categorized as having either worsening or no worsening pain if they did not meet any of the other end points for worsening pain).

RESULTS

Financial Evaluation

In the year before implementation of the ATI policy, 10% was the dominant strength of topical diclofenac product used in the health authority. After implementation of the ATI policy, topical diclofenac 2.32% was the dominant product (Table 1). The tipping point occurred approximately 7 months after implementation of the ATI policy (Figure 1).

In the year before implementation of the ATI policy, total expenditure on topical diclofenac 1.16%, 2.32%, 5%, and 10% was $280 154. In the year after implementation of the ATI policy, total expenditure was lower, at $112 023, a saving of $168 131. When data from the tipping point onward were used, the extrapolated expenditure for a full fiscal year was $71 288, which translated to a drug acquisition cost saving of $208 866 annually. This number represents the maximum possible saving, because our analysis did not take into account any new costs incurred for patients who experienced worsening pain (nursing labour, analgesic costs, etc.).

Retrospective Chart Review

A total of 51 patients were identified as receiving diclofenac in the study period. One patient was excluded because there was an 18-day gap between the last time 10% diclofenac was administered and the first time the 2.32% product was applied. None of the patients were receiving topical diclofenac 1.16%. This resulted in a study population of 50 patients. Patient characteristics are presented in Table 2. Agreement between the data extractors was 90%; for the 10% of data points for which discrepancies occurred, agreement was reached after discussion.

For 2 patients who did not meet components a–e and g of the primary outcome, medication records were unavailable, so we were unable to determine whether they had an increase in administration of other PRN analgesics (component f). Hence, the primary outcome was adjudicated for only 48 patients. Overall, 48% (23/48) of the patients met the composite primary outcome when analyzed according to scenario 1. When documented reasons for medication orders and administrations were taken into account, 5 patients met the component(s) of the primary outcome for reasons unrelated to the medical condition for which topical diclofenac was being used. Hence, when analyzed according to scenario 2, 38% (18/48) of the patients met the primary outcome. When the investigators examined each patient's entire clinical presentation, an additional 6 patients were considered to have met the component(s) of the primary outcome for reasons unrelated to the medical condition for which topical diclofenac was prescribed. Thus, when the primary composite outcome was analyzed according to scenario 3, 25% (12/48) of patients were considered to have met the primary outcome (Figure 2).

TABLE 1. Usage of Topical Diclofenac Products before and after Implementation of ATI Policy

	Study Period; No. of Units			
Topical Diclofenac Strength	**Pre-ATI (Jan 11, 2019 – Jan 9, 2020)**	**Post-ATI (Feb 7, 2020 – Feb 4, 2021)**	**Post-ATI after Tipping Point (Aug 21, 2020 – Feb 4, 2021)**	**Post-ATI Extrapolated[a]**
1.16%	687	107	49	106
2.32%	30	8619	5015	10 866
5%	2077	609	22	48
10%	9486	1761	1	2

ATI = automatic therapeutic interchange.
[a]Total usage in 1 fiscal year, extrapolated from data collected after tipping point.

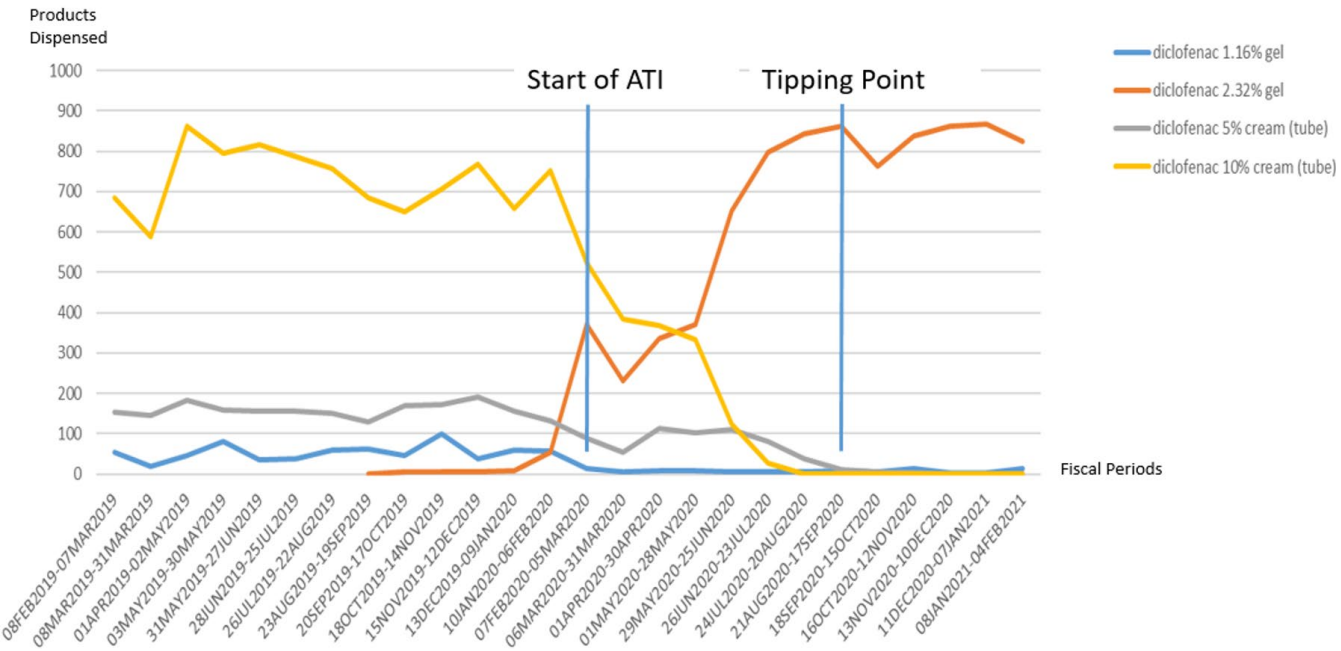

FIGURE 1. Monthly usage of topical diclofenac (number of units dispensed) before and after implementation of automatic therapeutic interchange (ATI).

TABLE 2. Patient Characteristics

Characteristic	No. (%) of Patients[a] (*n* = 50)
Location	
Langley Memorial Hospital	25 (50)
Ridge Meadows Hospital	12 (24)
Queen's Park Care Centre	5 (10)
CareLife Fleetwood	8 (16)
Sex	
Female	42 (84)
Male	8 (16)
Age (years)	
Mean	82.5
Minimum	45
Maximum	103
Site of application[b]	
Upper extremity (shoulder, arm, forearm, wrist, hand)	35 (70)
Lower extremity (hip, knee, thigh, ankle, leg, foot)	31 (62)
Torso (chest, abdomen, pelvis, back)	6 (12)
Neck	3 (6)
Joints	1 (2)
Soft tissue	1 (2)
Affected area (unspecified)	5 (10)

[a]Except where indicated otherwise.
[b]Sum of percentages exceeds 100% because some patients applied topical diclofenac to more than 1 site.

Findings for the secondary outcomes are shown in Table 3. Among the components contributing to the primary outcome, the most important were increases in the use of topical diclofenac PRN (component c) and other analgesics PRN (component f).

DISCUSSION

An interchange policy that switches any strength of topical diclofenac to topical diclofenac 2.32% resulted in substantial financial savings for the largest health authority in British Columbia, which serves approximately 3600 beds. The reliability of the financial evaluation is high, because data were based on the number of units issued by the pharmacy department, which is the only provider of medications for the health authority. We did not collect information about patient volume before and after implementation of the ATI policy. This information would have been useful to determine whether cost differences between the 2 study periods could be explained by a difference in patient volume. However, we feel confident that the savings are real, because roughly the same number of units were dispensed (about 900 units of topical diclofenac of any strength; see Figure 1) before and after the ATI policy was implemented, and the number of units dispensed is a reasonable surrogate for a comparison of patient volume between study periods. The exact value of the cost savings represents the maximum possible savings, because our analysis did not

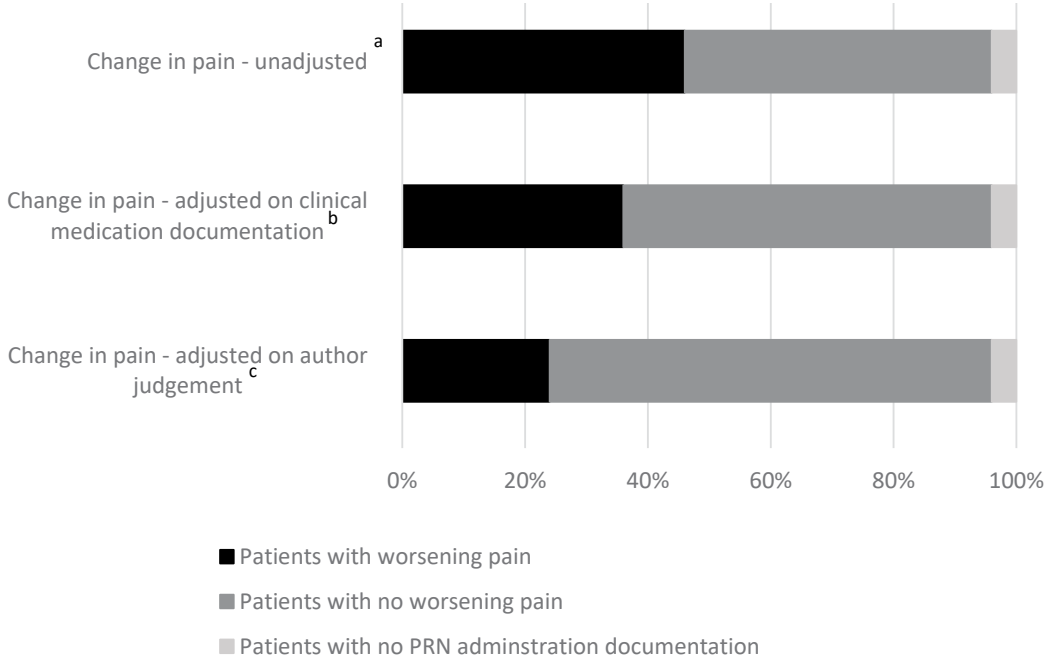

FIGURE 2. Primary outcomes (*n* = 50, including the 2 patients with no documentation of PRN administration). [a]Data based solely on medication orders and medication administration records. [b]Data based on medication orders, medication administration records, and documented reasons for medication administration or orders. [c]Data based on medication orders, medication administration records, documented reasons for medication administration or orders, and patients' clinical condition. PRN = as needed.

TABLE 3. Changes in Therapy for Patients with Indication of Worsening Pain after Switch to Lower Strength (2.32%) Topical Diclofenac

Secondary End Point	No. of Patients with Relevant Data[a]	No. (%) of Patients with Specified End Point
Regularly scheduled diclofenac		
Strength increase	48	0 (0)
Frequency increase	48	2 (4)
PRN diclofenac		
Strength increase	11	0 (0)
Frequency increase	11	0 (0)
≥ 30% increase in administered doses	11	4 (36)
New analgesic order	50	6 (12)
Regularly scheduled analgesic		
Dose increase	49	4 (8)
Frequency increase	49	1 (2)
PRN analgesic		
≥ 30% increase in total administered amount	36	14 (39)
Order changed to regularly scheduled analgesic	42	0 (0)

[a]Total number of patients for each secondary end point varies because of differences in patients' individual orders (e.g., some patients received only regularly scheduled diclofenac, whereas some received both regularly scheduled and PRN diclofenac).

take into account any new costs incurred for patients with worsening pain (nursing labour, analgesic costs, etc.). For example, a patient with worsening pain would need extra nursing assessment and would require doses of analgesics. Calculating these extra costs was beyond the scope of our evaluation; however, we believe these extra costs would be relatively small and would not negate the savings we identified. Notably, the retrospective chart review was conducted across multiple centres, which produced more generalizable findings. In addition, 2 investigators independently extracted the data for the retrospective chart review, which increased the accuracy of the data collected. The investigators also took a conservative approach and applied a low threshold for identifying patients who may have experienced worsening pain due to a reduction in topical diclofenac strength.

To our knowledge, this chart review is the first to provide any information on the possible comparative efficacy of high-strength and lower-strength topical diclofenac. We found that the majority of patients did not experience any worsening of pain (52%–75% of patients, depending on the analysis scenario) when switched from a higher strength of topical diclofenac to a lower strength. However, the proportion of patients with indicators for possible worsening of pain control was higher than we anticipated: we had arbitrarily assumed that less than 10% would have worsening pain because of the interchange policy, but the actual proportion was much higher. We did not prespecify the proportion of patients with worsening pain that would lead to discontinuation of the interchange policy, because we assumed it would not be a problem.

Most patients included in our chart review were switched to a lower strength of diclofenac during the COVID-19 pandemic, when visits and outings in long-term care facilities were restricted. After the chart review for the clinical evaluation, we discussed our findings with an experienced long-term care clinical pharmacy specialist, who provided useful insight into the interpretation of our findings in the context of the pandemic and its effects on the care of patients in long-term care. Pain is a multidimensional entity that is affected by biological, psychological, and social factors.[6] It is possible that the social isolation of patients during the pandemic had a negative effect on their mental health and well-being, which could in turn have led to more pain episodes and hence more use of PRN analgesics. As well, the pandemic limited nonpharmacological treatments for pain management, such as physical activities, so there may have been greater reliance on pharmacological interventions. Maxwell and others[7] reported a statistically significant increase in orders for opioids, especially hydromorphone, for residents in nursing homes during the pandemic. This finding suggests that the pandemic may have contributed to the higher-than-expected proportion of patients with worsening pain that we observed. However, given the retrospective nature of this chart review and the limited documentation in the charts, we do not know for sure whether any of the aforementioned issues were present for our study cohort.

In our opinion, of the components that constituted the primary outcome, the most concrete indicator of ineffectiveness of lower-strength topical diclofenac would have been reversion to a higher-strength product. None of the patients in our chart review had reversion to the higher strength of topical diclofenac; however, anecdotal reports indicated that some staff were under the impression that higher strengths of topical diclofenac could never be provided. We have now made clear to staff that higher strengths can be considered, on a case-by-case basis, for patients who do poorly with the 2.32% product. We feel that this approach reflects rational prescribing (i.e., start with a low dose and titrate to effect, which allows for identification of the lowest effective dosage for each patient).

Most of the patients in this analysis met the primary composite outcome because they had more PRN use of either topical diclofenac or other analgesics. The 30% threshold was arbitrary, and it may not represent a clinically significant increase in patients' pain. For example, a

patient with 1 use of PRN medication before the switch to lower-strength diclofenac and 2 uses after the switch had a 100% increase in PRN use, even though the absolute increase in PRN doses was small. Therefore, the proportion of patients with clinically significant increases in pain after the switch to lower-strength diclofenac may have been exaggerated. If PRN use of diclofenac and PRN use of other analgesics were omitted from determination of the primary outcome, only 10% (5/50) of the patients would have met the primary outcome according to scenario 3.

Considering that the majority of patients continued to have pain control with the lower strength of diclofenac, and given that the ATI policy produced large financial savings for the institution, the ATI policy has value. We therefore propose maintaining the ATI policy, as trialling a low-strength analgesic is appropriate for patients with no prior use of topical diclofenac. As per the ATI policy, clinicians may order a higher-strength product by indicating "do not substitute" on the prescription, which allows for reassessment and escalation of pain management as needed.

The main limitation of the chart review was its retrospective nature. The rationale for medication changes and PRN administrations was often not clearly documented. Furthermore, many patients receiving long-term care have cognitive impairment, which presents a challenge for conducting and documenting pain assessments.[8] The lack of data collector blinding to the purpose of the review may have introduced bias during data collection and analysis. Limitations to external generalizability of the study were age and gender, as we only considered patients in long-term care facilities, and the majority of these patients (84%) were female, whereas the proportion of female residents is 65% on average across all British Columbia long-term care facilities.[8]

CONCLUSION

An ATI policy that switches orders for higher-strength diclofenac to the 2.32% formulation resulted in substantial financial savings and led to worsening pain control in many patients (25%–48% of patients, depending on the scenario), but did not appear to affect pain control in the majority of patients (52%–75%). Worsening pain control can be managed as usual, on a case-by-case basis, by titrating to the lowest effective dose of topical diclofenac, with or without other analgesics. For some patients, a time-limited trial of the more costly compounded diclofenac (5% or 10%) may be warranted. At the study institution, it is now recommended that new orders specify the least costly topical product (2.32% topical diclofenac); more expensive forms of therapy can be trialled, as needed, for patients with poor response to this product. Future prospective studies comparing higher and lower strengths of topical diclofenac are warranted. We recommend that when other hospitals make changes to institutional policies (e.g., adding therapeutic interchanges), they should evaluate the clinical impacts in addition to the financial impacts.

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