ARTICLE

Stopping Medications in Complex Continuing Care: The Example of Baclofen and Dantrolene

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ABSTRACT

Background: Despite a lack of valid trials documenting their efficacy, baclofen and dantrolene are widely used to treat spasticity.

Objective: The primary purpose of this project was to evaluate the effects of planned withdrawal of baclofen and dantrolene in consenting patients who were receiving complex continuing care. We also surveyed physicians and patients (or their substitute decision makers) for the reasons they considered when deciding to participate in the withdrawal program.

Methods: In this descriptive study, data were collected before, during, and after the withdrawal intervention. A withdrawal protocol was used in which the clinical team performed individualized monitoring as a basis for making any withdrawal decisions.

Results: Of 69 patients taking either baclofen or dantrolene, 29 were excluded from the withdrawal protocol primarily because of physicians' decisions. Of the 40 eligible patients, 26 (65%) participated in the tapering protocol. Of these 26, 15 (58%) were able to discontinue the drugs, 6 (23%) had their doses reduced, 4 (15%) had no change in dose, and 1 patient died during tapering. Six (23%) had other changes made to their spasticity treatment, and 4 (15%) experienced improvements in other symptoms that could have been adverse effects of the antispasticity agents.

Conclusions: More than half of the participating patients were able to have baclofen or dantrolene discontinued or the dose lowered; some had adjustments in other medications. Targeted medication withdrawal programs can be used to reduce unnecessary medication in patients receiving long-term care in an institutional setting.

Key words: baclofen, dantrolene, complex continuing care, medication withdrawal, medication review

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RÉSUMÉ

Historique : Malgré le manque d'essais valides confirmant l'efficacité du baclofène et du dantrolène, ces deux agents demeurent largement utilisés pour traiter la spasticité.

Objectif : Le principal objectif de cette étude était d'évaluer les effets d'un sevrage planifié du baclofène et du dantrolène chez des patients consentants qui recevaient des soins continus complexes. Les médecins et les patients (ou leurs décideurs substituts) ont également été sondés pour connaître les raisons expliquant leur décision de participer au programme de sevrage.

Méthodes : Dans cette étude descriptive, les données ont été collectées avant, pendant et après le sevrage. Les décisions relatives au sevrage étaient fondées sur la surveillance individualisée des patients par l'équipe de soins cliniques, conformément à un protocole de sevrage.

Résultats : Parmi les 69 patients qui recevaient du baclofène ou du dantrolène, 29 n'ont pas été retenus pour suivre le programme de sevrage, principalement à cause de la décision du médecin. Des 40 patients admissibles, 26 (65 %) ont participé au protocole de diminution progressive des doses d'antispastiques. De ces 26 patients, 15 (58 %) ont pu complètement arrêter leur traitement, 6 (23 %) ont pu réduire leurs doses, 4 (15 %) ont conservé leurs doses initiales et un est décédé durant le traitement dégressif. Six patients (23 %) ont eu d'autres changements apportés à leur traitement antispastique et 4 (15 %) ont connu une réduction d'autres symptômes qui auraient pu être des effets indésirables des antispastiques.

Conclusions : Plus de la moitié des participants ont réussi leur sevrage de baclofène ou de dantrolène ou une réduction de leur dose de ces médicaments; certains ont eu des ajustements à leurs autres médicaments. Les programmes de sevrage médicamenteux ciblés peuvent servir à réduire l'utilisation inutile de médicaments chez les patients en centres hospitaliers de soins de longue durée.

Mots clés : baclofène, dantrolène, soins prolongés complexes, sevrage médicamenteux, revue des médicaments

INTRODUCTION

This article describes the outcomes of a tapering protocol for withdrawal of baclofen and dantrolene that is used in the Complex Continuing Care Program at the authors' institution. The SCO Health Service in Ottawa, Ontario, has 348 complex continuing care beds, 98 rehabilitation beds, 36 palliative care beds, and 269 long-term care beds. Patients are admitted to the Complex Continuing Care Program with a wide variety of debilitating conditions. Some need institutional care for many years, and others are eventually rehabilitated to a lower level of care.

The authors' institution is recognized for its well-trained, competent health care professionals (e.g., physicians, physiotherapists, occupational therapists, nurses, pharmacists) and involved caregivers (e.g., family, and friends) who collaborate closely on a daily basis.

The problems associated with the high level of inappropriate prescribing for patients receiving long-term institutional care[1-3] and the success of a cisapride tapering protocol at the authors' institution[4] have been previously reported. Specifically, a withdrawal protocol was successful in stopping cisapride therapy for 23 (66%) of 35 patients, without any adverse consequences.[4] This led to a belief that a Targeted Medication Withdrawal Program would be a useful addition to regular medication review tools at the institution. It was postulated that the use of an institution-wide withdrawal program with standard tapering recommendations and individualized monitoring protocols and with explicit support from the Pharmacy and Therapeutics Committee would support health care professionals in making decisions to withdraw medications that might not be helping patients.

A Drug Utilization Task Force was assigned responsibility for determining drugs that should have priority for medication withdrawal. After cisapride, the next group of drugs identified for possible withdrawal were the antispasticity agents baclofen and dantrolene.

Placebo-controlled and comparative trials attempting to document the efficacy of oral antispasticity agents have yielded inconclusive results.[5,6] In many instances, this is because of the variability of spasticity and the lack of a sensitive, reliable, and functionally and symptomatically relevant assessment tool. Despite the inconclusiveness of the research, these agents remain in wide use, and many caregivers and patients have a clinical impression that the drugs work. As such, there appears to be a wide gap between the published evidence and the daily experience of those managing spasticity.

In addition to the lack of objective evidence for effectiveness, antispasticity agents are associated with significant side effects. The common side effects of baclofen include drowsiness, vertigo, psychiatric disturbances, insomnia, slurred speech, ataxia, hypotonia, and weakness. These side effects are dose related, and elderly patients are at higher risk, particularly for side effects affecting the central nervous system. The common side effects of dantrolene include drowsiness, dizziness, lightheadedness, fatigue, rash, diarrhea, nausea, vomiting, and muscle weakness.

More than 80 complex continuing care patients were taking one or both of the targeted drugs at the time the proposal for this study was submitted (June 2002). The main indications were spasticity and contractures due to a variety of causes, including multiple sclerosis, cerebral palsy, spinal cord injury, ankylosing spondylitis, brain injury, and cerebral bleeding. The stage and severity of the conditions varied widely, and treatment of the spasticity and contractures was indicated for a variety of reasons: to reduce pain, to reduce spasms, to facilitate nursing care, to enable seating and to maintain or improve mobility.

At the time, approximately $25 000 was spent annually on baclofen and dantrolene at the SCO Health Service. Under the direction of the Drug Utilization Task Force and the Medical Advisory Committee, the Pharmacy and Therapeutics Committee was charged with attempting to limit use of these medications while maintaining quality of care for patients.

Through discussion with physicians and pharmacists working in the Complex Continuing Care Program, it was determined that attempts were not routinely made to discontinue baclofen or dantrolene, even when their efficacy was unclear. This might have been due to the need for gradual withdrawal and individualized monitoring to prevent medication withdrawal reactions, anticipated worsening of symptoms on withdrawal, or increased care requirements because of changes in the patient's condition. To find out more about this hesitancy to withdraw medications in the face of limited evidence of usefulness, a short oral survey was administered to physicians and patients (or their substitute decision makers) to ask why they might or might not want to participate in a withdrawal protocol for these medications.

The specific objectives of this study were

- to evaluate the effects of planned withdrawal of baclofen and dantrolene in consenting complex continuing care patients
- to determine the proportion of patients for whom it was possible to taper or withdraw baclofen or

dantrolene without negative effects
- to determine whether any symptoms potentially caused by baclofen or dantrolene improved or resolved with tapering or discontinuation of the medication
- to determine if any demographic variables were predictive of successful withdrawal
- to describe changes in other spasticity-related therapy during medication withdrawal
- to describe the factors considered by physicians and patients (including substitute decision makers) when deciding whether or not to participate in the withdrawal program.

METHODS

A withdrawal protocol template, involving weekly 50% dose reductions at the discretion of the clinical teams, was developed for both baclofen and dantrolene. The proposed monitoring parameters included but were not limited to the following:

- a measure of spasticity (e.g., Ashworth score, clonus score)
- assessment of pain (e.g., rating of pain, on a scale of 0 to 10, using faces pain scale; use of "as needed" pain medications)
- measures of physical function (e.g., ease of seating in wheelchair, ease of perineal care, ability to feed self, positioning in bed)
- documentation of any symptoms that could have been related to these medications and that improved upon tapering or discontinuation of the drugs

Because spasticity was caused by a variety of conditions in these patients and because the patients were at different stages of their diseases, it was felt that the patients' clinical teams would be in the best position to design the individualized monitoring plan for each patient. Thus, although the monitoring plans needed to address the four main categories listed above, the specific measures for each category could differ from one patient to another.

The study was descriptive, with data being collected before, during, and after the intervention. Results are presented in terms of proportions.

Two questionnaires, one for physicians and the other for patients or their substitute decision makers, were developed to determine the reasons for having patients participate or not participate in the withdrawal program. These questionnaires were administered orally, with the research assistant asking the following questions:

- To each physician for each of his or her patients: "What reasons or factors did you consider when deciding if this patient should be included in or excluded from the withdrawal protocol?"
- To each patient and/or substitute decision maker: "What are your reasons for participating in this medication withdrawal?" or "What are your reasons for not participating in this medication withdrawal?"

A physician consent process (both to have their eligible patients participate in the withdrawal protocol and to themselves participate in the questionnaire) and a patient or substitute decision maker consent process (both to participate in the withdrawal protocol and to participate in the questionnaire) were developed.

Approval to carry out the project was received from the SCO Health Service Research Ethics Board. The responsibilities of the research assistant (V.P.) for this study were to conduct education sessions for health care professionals, carry out the physician and patient consent process, guide development of the patients' individualized monitoring plans, assist with documentation, and maintain the study binders.

Education sessions for the pharmacists, physiotherapists, occupational therapists, and nurses covered the study rationale and methods. These provided an opportunity for staff to ask questions and clarify concerns. A study information sheet stating the rationale and methods was distributed to each physician. Physicians were also informed about the study (including the results of the Cochrane collaboration reports[5,6]) through the normal committee structure of the institution (i.e., meetings of the Pharmacy and Therapeutics Committee, the Medical Advisory Committee, and medical staff).

Potential subjects for the study were identified from pharmacy medication records. Patients were considered eligible if they were receiving either baclofen or dantrolene or both. It was initially thought that the study should exclude any patients who had had recent (in the previous 6 months) dose changes of baclofen or dantrolene, a switch from one agent to the other, or an unsuccessful withdrawal trial, but the physicians felt that these criteria were too restrictive and they wanted to include these patients for consideration as well. A list of their potentially eligible patients was developed for each physician. The research assistant met with each physician to review the list and determine the appropriateness of baclofen or dantrolene withdrawal for each patient. At that time, the physician's reasons for recommending patients for study inclusion or exclusion were documented. The physician was also asked who

should be approached for consent: the patient or a substitute decision maker or both.

The physician consent process happened at the beginning of the study, when the patient lists were reviewed. The patient consent process occurred gradually during the study, as staff wanted to only enroll a few patients at a time. The research assistant sought each patient's consent just before medication withdrawal for that patient began. At the time of seeking patient consent, the patient's pharmacist introduced the research assistant and described the project concept; the research assistant then explained the study and requested written consent.

The baseline data collected for each consenting patient were age, sex, main diagnosis related to use of baclofen and/or dantrolene, and current dose of baclofen and/or dantrolene.

Once patient consent had been obtained, the patient's physiotherapist, occupational therapist, pharmacist, and nursing representative (and occasionally the physician, if he or she was present in the institution that day) met with the research assistant to develop an individualized monitoring plan and to determine the frequency of monitoring. The interdisciplinary team incorporated tools and approaches already in use with the patient (such as the Ashworth or clonus score) or provided useful information to guide decision-making (e.g., pain assessment, because most patients experienced pain in association with spasticity). Each team was also able to identify individualized monitoring parameters related to function. Because spasticity always affects function, at least one important functional parameter was included for each patient. The patient and/or lay caregiver also had an opportunity to contribute to the development of the monitoring plan. The monitoring documentation forms were kept in convenient locations for the nurses (with the medication administration record), therapists (with other patient documentation), and the patients or caregivers (at the bedside). Dates for starting the medication withdrawal, the decision about which drug to withdraw first (for patients who were taking both medications), and subsequent decisions regarding the magnitude and frequency of dose changes (and other changes in therapy) were made by the health care team and were based on the data in the individual monitoring plans.

The team for each patient met regularly (once or twice a week initially, then as needed) to discuss the patient's progress, to inform each other of adaptations made to patient care to manage changes in spasticity or other resolving adverse effects, and to determine whether tapering should continue. Each team member shared his or her knowledge of the patient's progress, and the group used a shared decision-making approach to determine whether further dose changes were appropriate. The physician was contacted as appropriate to convey information about the patient's condition and to suggest drug changes. The dose of the drug being withdrawn was reduced until spasticity reappeared or became worse, tone increased, and/or function decreased. If any of these endpoints occurred, the dose was then increased gradually to a point where there was an improvement in spasticity, tone, and/or function. The pharmacists worked closely with the physicians to provide individualized pharmacological information to aid in decision-making regarding alternative medication for spasticity. These individualized recommendations varied according to the patient's disease, the stage and severity of the condition, other medications and disease states, previous medication responses, and acceptability to the patient.

Monitoring and documentation continued for 4 months after the drug was withdrawn or a maintenance dose had been established. At the end of this period, the patient's chart was reviewed to document other changes in therapy related to spasticity treatment.

RESULTS

Patient enrollment began in November 2002, and all eligible patients had completed the withdrawal protocol and monitoring period by July 2004.

At the time the project was started, 69 patients in the 348-bed complex continuing care unit were taking either baclofen or dantrolene or both. Twenty-nine of these patients were excluded from the study primarily because of physicians' reasons; one physician declined to participate in the study, which affected 9 patients. Participating physicians judged the remaining 20 patients as ineligible for a variety of reasons, including the following:

- the medication seemed to be working (n = 9)
- the family was concerned about making changes to medication (n = 4)

Common reasons for recommending inclusion in the study for the remaining 40 patients included the following:

- patient seemed stable, and physician was unsure whether medication was needed (n = 23)
- to decrease the number of medications (n = 13)
- to potentially minimize adverse effects (n = 6)

Of the 40 eligible patients, 26 (65%) agreed to participate in the withdrawal process. Common reasons for participating were the following:

- withdrawal may be of benefit to the patient (n = 14)
- to decrease number of medications (n = 9)
- research is important for the benefit of future patients (n = 8)
- to decrease side effects (n = 7)
- not sure if the medication is having any effect (n = 5)

Among the patients or substitute decision makers from whom it was not possible to obtain written consent, 2 patients died before they could be approached, 2 substitute decision makers could not be reached or did not return the written consent form despite verbal agreement, and 10 patients (or substitute decision makers) decided not to participate. The most common reason for not wanting to participate, cited by all 6 of the patients or substitute decision makers who agreed to answer the questionnaire but declined to participate in the withdrawal protocol, was that the medication seemed to be working.

An example of an individualized monitoring plan is shown in Appendix 1. Early in the project, it took up to an hour for the clinical team to develop such a plan for each patient. However, as the project progressed and staff became familiar with both the project and the effects of medication withdrawal, it took less time to develop a monitoring plan, and by the end of the project, a monitoring plan could be devised by 4 team members in 10 min. Examples of typical monitoring parameters used by the teams are outlined in Table 1.

Of the 26 participating patients, 15 (58%) had baclofen or dantrolene discontinued. Six (23%) were maintained on a lower dose. Four (15%) were maintained on the same dose. Six (23%) of the patients had other changes made to their spasticity treatment, such as

- increase in gabapentin dose
- addition of tizanidine

Table 1. Examples of Monitoring Parameters Used for Different Patients and Who Did the Monitoring

Variable	Assessor
Spasticity	
Ashworth score[7]	Physiotherapist
Clonus score	Physiotherapist
Spasm frequency	Nursing staff
Spasm severity	Nursing staff
Stiffness of left hand (distance that hand can be opened, from fingertips to palmar crease, in centimetres)	Physiotherapist
Stiffness (e.g., when trying to help patient into car, leg sometimes too stiff to bend)	Family member
Worsening of spasm	Mother
Pain	
Rating from 0 to 10 using faces pain scale	Nursing staff, personal care workers
Use of analgesics as needed (prn)	Pharmacist
Foot pain leading to request for more pillows under feet in bed	Nursing staff
Functional status	
Ease of perineal care (e.g., abduction of hips)	Nursing staff
Positioning in wheelchair	Occupational therapist, nursing staff
Seating (general)	Nursing staff
Seating (ability to flex at hips)	Occupational therapist
Ability to remove and put on eyeglasses	Physiotherapist
Ease of rolling patient in bed	Nursing staff
One-person assist from front to help patient stand from wheelchair	Physiotherapist
Standing transfer	Nursing staff
Range of motion (e.g., upper extremities, elbows, knees)	Occupational therapist
Fit of hand devices	Occupational therapist, nursing staff
Ability to stand on tilt table	Physiotherapist
Position of left foot on foot plate	Occupational therapist
Position of left arm on tray	Occupational therapist
Ease of dressing	Nursing staff
Increased stiffness of left hand causing inability to use handroll	Occupational therapist
Ability to finger feed	Nursing staff
Ability to walk with walker	Nursing staff
Stiffness in hands and legs when doing evening exercises	Husband

- addition of botulinum toxin, clonazepam, and acetaminophen (for a patient who remained on baclofen but at a lower dose)
- addition of botulinum toxin and clonazepam (for a patient who remained on baclofen but at a lower dose)
- addition of botulinum toxin (for a patient who remained on the same dose of baclofen)
- addition of acetaminophen and tizanidine added (for a patient who remained on the same dose of baclofen)

None of these changes were attributed specifically to the dose reductions of either baclofen or dantrolene and may have been related to disease progression and active clinical management to improve symptom control. Decisions about adding other pharmacological agents were made by the physicians and pharmacists and reflected their knowledge of the patient, the disease state, the stage and severity of disease, affected limbs, other medications, and previous response to medications. There was no overall change in the pharmacy budget for either botulinum toxin or tizanidine over the course of the study.

Four (15%) of the 26 participants had improvements in other symptoms that could have been adverse effects of the antispasticity agents. These were identified by the pharmacist for each individual patient as part of usual monitoring responsibilities and were determined by the pharmacist to have been as a result of tapering the antispasticity agent (rather than stopping another sedating drug or some other reason). The respective improvements noted for each patient were

- increased alertness
- improved level of communication, more interaction with others, less drowsiness
- more facial expressions, a more cheerful mood, more smiling
- improved muscle strength and a louder voice (for a patient who eventually started back on a small dose of baclofen)

One patient died during tapering because of disease progression.

The demographic characteristics of the participating patients (except for the patient who died) are listed in Table 2. The results of enrollment and medication withdrawal are outlined in Figure 1. No demographic variables were found to be predictive of successful withdrawal.

Table 2. Characteristics of Participating Patients

Characteristic	No. of patients*
Sex	
Male	10
Female	15
Age (years)	
<60	13
>60	11
Mean (range)	60.2 (33–81)
Condition	
Multiple sclerosis	12
Cerebrovascular accident	6
Head injury	3
Subarachnoid hemorrhage	2
Spinal cord injury	1
Cerebral palsy	1
Drug	
Baclofen	19
Dantrolene	5
Both	1

*Sample size = 25 patients, except for age, where sample size = 24.

DISCUSSION

A majority (81%) of the eligible patients who consented to participate in baclofen and dantrolene withdrawal were able to stop or minimize the dose of the medication; some patients experienced improvement in associated side effects. These results are similar to those seen in the earlier cisapride withdrawal project[4] and confirm that periodic attempts to stop medications in patients receiving long-term institutional care are reasonable.

The earlier study used a 2-week follow-up period after medication withdrawal, but it was felt that this period was too short to judge the full effect of stopping a medication. A 4-month follow-up period seemed more reasonable to accurately judge the effect, but health care staff found that documentation during this time was tedious. This concern was addressed by reducing the frequency of monitoring during the latter part of the follow-up period. For instance, the team initially monitored parameters once or twice weekly, but once the last dose of baclofen or dantrolene had been given, the frequency of monitoring was halved (e.g., to once every 2 weeks). Six weeks after the last dose, the frequency was halved again (e.g., to once every 4 weeks). Ten weeks after the last dose, the frequency was halved for the remainder of the 4- month period (e.g., to once every 8 weeks). If there were changes in the patient's condition at any time during the withdrawal or follow-up period, the monitoring plans were discussed. These discussions occurred in person (during regular and impromptu meetings), by telephone, or by e-mail.

The reasons for participating in the medication withdrawal study seemed to relate to a few distinct

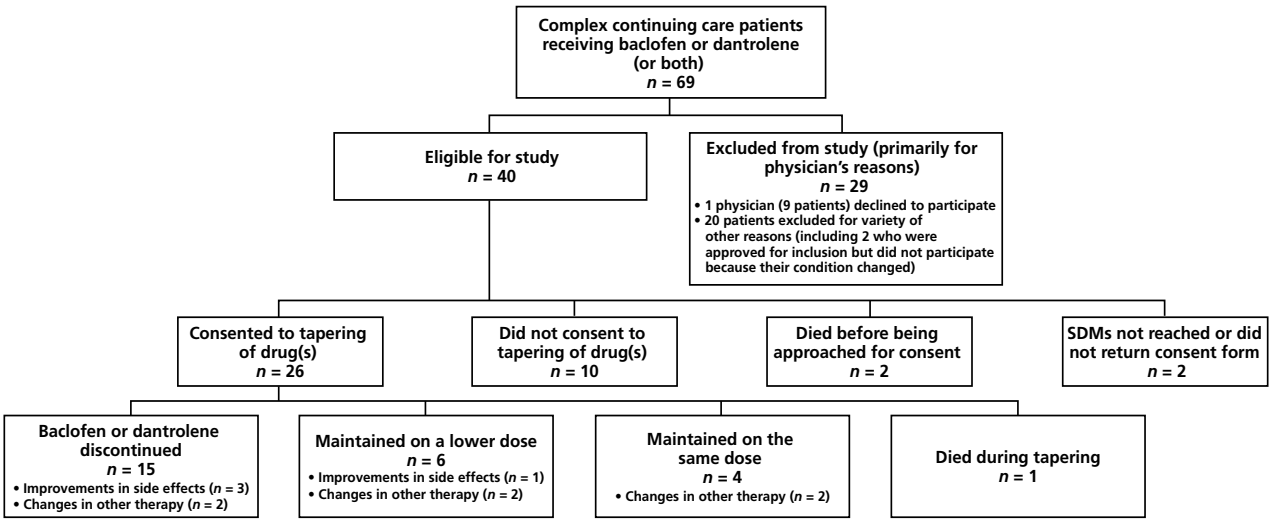

Figure 1. Flow chart depicting patient enrollment and outcomes. SDM = substitute decision maker.

themes. Physicians generally did not recommend patients for whom they felt the medication was clearly working. We did not ask them to describe how they felt the medication was benefiting the patient. They also excluded patients whose families typically did not like changes in medications. Interestingly, the main reason for including patients was that the patient was stable and it was unclear if the medication was needed. This reason contrasts with anecdotal reports of reluctance to change medications when the patient seems stable. Perhaps the development of a standard tapering protocol and an individualized monitoring plan involving the whole team were factors that allowed physicians to feel more comfortable in making a change for an otherwise stable patient. This argues for continuation of the Targeted Medication Withdrawal Program. Patients and their substitute decision makers were hopeful that the medication tapering might somehow offer benefits to the patient. Surprisingly, many patients and substitute decision makers identified the need to participate in research for the benefit of future patients as a key reason for their own participation. For these patients to be so concerned about the lives of others was humbling. A few patients thought that they might be experiencing adverse effects, and a few doubted the effectiveness of the therapy. These results are descriptive at best but warrant further investigation. Much research has been performed and published about the decision-making process when a patient starts therapy, but very little has been done to describe how physicians, patients, and families make decisions about reassessing and stopping therapy. In an age when medications are being used more and more often and when inappropriate use is common, more information is needed about how to identify when therapy is no longer effective and how to influence physicians' and patients' decision making about stopping therapy.

Pharmacists, working with the other health care professionals, determined that 4 patients had adverse effects that improved with tapering or withdrawal of the antispasticity agent, including improvements in alertness and communication and, notably, an improvement in muscle strength that resulted in a patient being able to lift his hand to push a wheelchair door button. While this may seem a small accomplishment to some, it created a significant change in quality of life for the patient, as it allowed him to move around the hospital more easily. Increased alertness and communication were viewed positively by some and negatively by others, who felt that the patients would benefit from more sedation.

The limitations of this study included the small sample size and the variation in disease states and symptom severity. This variation made it impossible to analyze any predictors of successful withdrawal. The lack of appropriate, validated, and reliable spasticity evaluation scales applicable to all disease states makes it difficult to assess the effectiveness of therapy if one is monitoring efficacy with a single perspective. In this study, broadening the evaluation to include individualized

measures of function and pain helped to overcome the limitations of the available tools for measuring spasticity. The results of this study are descriptive only, and there was no control group. One physician declined to participate even though the Pharmacy and Therapeutics Committee and the Medical Advisory Committee supported the study. This limited the sample size further. Neither the patients nor the caregivers were blinded to the tapering process, which could have resulted in reporting bias. For example, some staff might have had preconceived notions that the monitoring parameters would worsen or improve with tapering. However, these potential biases were likely minimized by the multidisciplinary approach to monitoring and decision-making.

Some challenges were encountered in carrying out the project. Obtaining patient consent was often difficult because of the frequent need to arrange meetings with substitute decision makers. Some of the substitute decision makers did not visit routinely and were not available during the week or daytime. Enrolling patients was hampered by health care professionals' concerns about an increase in workload. This limited the number of patients who could be enrolled at any one time and increased the overall duration of the project. Two patients who had originally been approved by their physicians for inclusion in the study had the approval withdrawn before enrollment because their condition deteriorated. It was initially difficult to arrange clinical team meetings to develop the individualized monitoring plans, but this problem abated as the team members became more familiar with how to design these plans and the research assistant exercised flexibility in her approach to how these meetings could occur. Completing and using the monitoring plan documentation was difficult. It was time consuming for staff, rotating nursing staff were reluctant to document, and non-nursing staff kept their documentation with their own clinical notes (making it hard to track down the information). In future, for any similar research project, funds would be allocated to pay for the time of health care professionals spent developing, using, and documenting the individualized monitoring plans.

Overall, most physicians and health care staff supported the study wholeheartedly. The standardized tapering protocol and implied institutional support may have provided needed support to physicians deciding whether to attempt withdrawal. The use of individualized monitoring plans and involvement of the clinical team created a feeling of assurance that any changes would be noticed and that any necessary action could be taken quickly. Being able to depend on all of the involved health care professionals to do appropriate monitoring and report their findings enabled physicians to be comfortable with the withdrawal process, which may have encouraged buy-in from both physicians and patients. Use of individualized monitoring plans provided a patient-centred approach to medication withdrawal, close and frequent monitoring (which may not occur in regular practice), an opportunity for patients and family members to be actively involved in care, and an opportunity for the health care team to work closely together in the evaluation of medication changes.

Over $3000 annually was saved among the study patients through dose reduction or discontinuation of baclofen and dantrolene. Continued attempts to reduce medication to minimally effective doses is important in attempts to limit the growth of the institution's drug budget.

The pragmatic approach used in this study allowed inclusion of a wide variety of patients with different diseases and different affected body parts. Individualized monitoring plans were used in the context of regular clinical care and included measures of spasticity as well as measures of functional impairment and pain that were relevant to the patient and the caregivers. This approach is consistent with literature recommendations that the evaluation of spasticity and its effects be comprehensive in scope and go beyond the use of only one scale to assess change in spasticity (e.g., the Ashworth scale) to assess how change in spasticity affects function.[7,8] Although this approach did not support the type of quantitative evaluation done in the typical phase 2 or phase 3 drug trial, it did allow measurement of endpoints that were meaningful to individual patients.

The success of baclofen and dantrolene withdrawal reported here lends support to continued use of Targeted Medication Withdrawal Programs in the authors' institution. Institutional support, combined with a formal structure for medication withdrawal, detailed monitoring parameters, and assurance of follow-up, allows physicians, pharmacists, and other health care professionals to more easily make decisions to reassess medication efficacy in their patients.

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Appendix 1. Example of Individualized Monitoring Plan

Patient Name: **Drug being tapered:**

Patient Number:

1. Monitoring Parameter 2. Responsibility 3. Frequency of Monitoring	Baseline value Date	Week ending	Week ending	Week ending
Pain Scale – pain with morning care or repositioning Monitored by: RN/RPN Frequency: twice weekly (see faces pain scale attached)				
Pain causing use of prn analgesics Monitored by: pharmacist Frequency: once weekly				
Measure of functional status: Lifts hand from chest to mouth for feeding (s=same, b=better, w=worse) Monitored by: mother Frequency: twice weekly				
Measure of functional status: Positioning in wheelchair (s=same, b=better, w=worse) Monitored by: occupational therapist Frequency: once weekly				
Ashworth score 0 No increase in tone 1 slight increase in tone giving catch when limb is moved in flexion or extension 2 more marked increase in tone but limb easily flexed 3 considerable increase in tone, passive movement difficult 4 limb rigid in flexion or extension Monitored by: physiotherapist Frequency: once weekly (Tuesday)				