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Original Article

Continuing Medical Education-Driven Skills Acquisition and Impact on Improved Patient Outcomes in Family Practice Setting

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Abstract

Background: *An abundance of educational theory, design, and delivery of continuing medical education (CME) learning interventions, including their impact on learners, are described in the health and social sciences literature. However, establishing a direct correlation between the acquisition of new skills by learners and patient outcomes as a result of a planned CME learning intervention has been difficult to demonstrate.*

Methods: *The learning intervention described here tested the impact of an injection skills-acquisition program for family physicians treating osteoarthritis of the knee by measuring patient outcomes using the pain and function subscales of the Western Ontario and McMaster (WOMAC) 3.0 osteoarthritis index, a standardized and fully validated patient-centered outcome measurement. It was hypothesized that patients of family physicians who participated in this skills-acquisition CME program would benefit from treatment administered by their physician during the time between injection skills acquisition to 6 weeks post-injection. Inclusion of a validated health status measure administered pre- and post-injection in addition to more traditional faculty and participant program evaluations was deemed necessary to test this hypothesis. Rheumatology, orthopedic surgery, and family medicine specialists from across Canada were invited to contribute to the planning, curriculum elaboration, and delivery of the viscosupplement injector preceptorship (VIP) program. Thirty-nine orthopedic and rheumatology specialists agreed to serve as expert faculty and participated in training 474 Canadian family and general practitioners over 8 months. The learning intervention involved a review of pertinent literature by a local preceptor and a summary of recommendations of the planning committee, followed by demonstration of injector skills and then supervised practice with patients, who received hylan G-F 20 (Synvisc™, Ridgefield, NJ) usually in the offices of the family physicians. The pain and function subscales of the WOMAC 3.0 questionnaire were self-administered to each patient in their physician's office, prior to receiving their joint injection and again at or near 6-weeks post-injection. Data were analyzed in the Department of Epidemiology and Biostatistics at The University of Western Ontario, London, ON.*

Results: *Clinically important statistically significant improvements in pain and physical function were noted in patients who received viscosupplementation treatment from family physicians who had recently acquired the necessary injection skills. Approximately three-quarters of the*

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patients experienced a reduction in pain and an improvement in physical function of at least 20%.

Implications: *These results suggest a positive relationship between acquisition of a new skill by learners and improved patient outcomes as a result of this planned CME learning intervention.*

Key Words: Continuing medical education (CME), family physicians, injection, measurement devices, patient outcomes, skills acquisition, validation, viscosupplementation, WOMBAT, WOMAC

An environmental scan of the continuing medical education (CME), rheumatology, and orthopedic literature and input from expert preceptors from across Canada revealed there is no standardized country-wide undergraduate or postgraduate curriculum or other well-defined educational process for acquiring joint injection skills.[1] For most family physicians, these skills seem to be acquired on a rheumatology or orthopaedic rotation as an undergraduate, intern, or resident, or from a colleague while in practice. A needs assessment conducted among 44 family physicians in southwestern Ontario indicated that 59% were interested in acquiring knowledge about joint injection, of which half expressed particular interest in viscosupplementation. This article reports the development of a knowledge- and skills-based CME program. The impact of the program on participating family practitioners and on the patients they subsequently treated with their newly acquired skill was also evaluated.

Methods

A curriculum-elaboration meeting was organized, involving seven medical specialists in orthopedic surgery, rheumatology, and family medicine; these specialists also formed a steering committee. This group was to provide professional input in the development of a curriculum for injection training of family physicians and elaborate the scope and dimension of a suitable learning intervention, including an instruction manual and participant workbook along with other relevant CME materials. A 1-day meeting was held to define target audience needs, training group size, faculty qualifications, training locations for physician instruction, patient qualifiers, evaluative mechanisms, and incentives. It was also agreed that viscosupplementation with hylan GF 20 (Synvisc™, Ridgefield, NJ), an injectable form of osteoarthritis therapy, would be used in the training of family physicians.

A viscosupplement injector preceptorship (VIP) program skills acquisition manual (SAM) was developed with input and review from the steering committee. The SAM was to serve as both a guide for expert faculty and a resource for participants: it included information on basic anatomy of the knee, diagnosis of knee osteoarthritis, treatment guidelines for knee osteoarthritis, and patient selection criteria for viscosupplementation with Synvisc™. Sections addressing mode of action, clinical and adverse effects, warnings and contra-indications to Synvisc™ treatment, and practical pointers were also included. Issues concerning use of injectable corticosteroids were also addressed for the same areas as for viscosupplementation. The remainder of the manual provided practical tips for giving injections and for the prevention and management of adverse reactions, and troubleshooting guidelines. The manual also included samples of all evaluative mechanisms (pre- and post-injection pain and function subscales of the Western Ontario and McMaster [WOMAC] 3.0 questionnaire, faculty expert preceptor-program evaluation, and participant-

preceptor program evaluation questionnaires) and an extensive reference list of peer-reviewed literature. The WOMAC index is widely used, and is a valid, reliable, and responsive self-administered tridimensional health status measure for knee and hip osteoarthritis studies, available in visual analogue and adjectival formats in over 30 different languages.[2]

Faculty trainers (expert preceptors) were contacted by a third party (KARMA® Clinical Relations Canada Inc.) to participate in the program. Faculty identification was based on market research and intelligence provided by the supporting pharmaceutical and device manufacturers, and used the following criteria:

- Specialist or family physicians who have particular skills in injection techniques, primarily in the knee;
- Physicians who possess advanced knowledge of principles of viscosupplementation and its mode of action and success rates, and have used viscosupplementation in the past month;
- Physicians who have successful experience with Synvisc™;
- Physicians who are local experts in osteoarthritis of the knee as evaluated by local family practitioners; and
- Physicians who are interested in CME and in teaching other physicians and health care professionals.

Forty potential expert preceptors were contacted by telephone and interviewed to determine their suitability, interest, and availability to participate in the learning intervention; 39 agreed to participate. Each subsequently met with members of the steering committee either personally or by conference call to discuss the program. Each received a SAM prior to follow-up contact to familiarize themselves with the instruction materials that participants would receive before their training session.

Participants (family practitioners) were identified and contacted by representatives of the pharmaceutical and device manufacturers, and were invited to attend the VIP sessions by the following criteria, evaluated in a personal interview:

- The family practitioner expressed an avid interest in acquiring joint-injection techniques to the representative;
- Viscosupplemenation was not currently used for osteoarthritis therapy in the family practitioner's practice, primarily due to lack of expertise in joint injection;
- The family practitioner was willing to devote 4 hours to participating in a training session;
- The practitioner could provide a patient with osteoarthritis of the knee(s) who was amenable to joint injection;
- The practitioner would participate in the evaluation process (pre- and post-injection WOMAC 3.0 questionnaires); and
- The family practitioner would continue self-directed use of the injection skill to maintain competency.

Representatives then organized a training session for three to five family practitioners and a local expert preceptor; this is an effective format to enhance learning.[3] Each session was conducted in the clinical practice of the participants, which, although variable, always was one of the following: the preceptor's offices or group-practice clinic; the expert preceptor's private practice, or a hospital. A typical training session consisted of a small-group interactive learning session followed by live patient injection-technique demonstration and practice, all taking place over approximately 4 hours. Each family physician was required to bring one patient with osteoarthritis of the knee(s) and the patient's x-rays to the training session. Prior to injection, participants supervised the administration of pre-injection WOMAC 3.0 questionnaires to their patients and the expert preceptor re-examined each patient and confirmed the

osteoarthritis diagnosis and suitability for visco-supplementation therapy. The practical work began when the expert preceptor determined that the group felt ready to begin injecting. Each family practitioner injected their own patient under the supervision of the expert preceptor, while being scrutinized by their peers. Since a full course of Synvisc™ requires three intra-articular injections administered 1 week apart, the preceptor was available to the family practitioner should difficulty be encountered during subsequent injections. In only 9 of 445 (2%) cases did a family practitioner contact the expert preceptor for additional training or to request that the expert preceptor perform the follow-up injections on their patient. An average of four family practitioners participated in each training session, with 96 individual sessions completed in 6 months across Canada.

A second objective of this study was to validate a patient global assessment question for future incorporation into a modified WOMAC 3.0 index, that we have provisionally termed the Western Ontario Measurement Battery (WOMBAT 3.0). If successfully validated, the WOMBAT 3.0 would contain the WOMAC pain and physical function subscales, and a patient global assessment of knee osteoarthritis subscale. In contrast to the WOMAC 3.0, the WOMBAT 3.0 would not contain a stiffness subscale. This modification was to accommodate recommendations made at the OMERACT III Conference[4] and in the Ostearthritis Research Society guidelines document[5] in which pain, function, and patient global assessment (but not stiffness) were established by international consensus as core set clinical variables for future osteoarthritis studies. The WOMAC 3.0 and the patient global assessment question were prepared in adjectival (Likert) format, in both English and French for Canada, and combined in a single questionnaire, hereafter referred to as the WOMAC/PGA questionnaire.

Data were coded, entered, and analyzed in the Department of Epidemiology and Biostatistics at the University of Western Ontario using the SAS program.[6] Descriptive statistics were used to characterize responses to the three questionnaires. The statistical significance of the treatment effect was evaluated using both parametric (Students *t* test) and nonparametric (Wilcoxon Signed Rank test) methods. Previous comparisons of these two approaches using the WOMAC Index has not shown important differences in levels of significance or data interpretation.

In order to validate the patient global assessment question, the approach captured by the OMERACT Filter was used.[7] The OMERACT Filter for selecting outcome measures places emphasis on those that fulfill criteria for truth (validity), sensitivity (responsiveness + reliability), and feasibility. Validity was assessed by testing convergent construct validity between patient global assessment scores and WOMAC pain and function subscale scores. Sensitivity was evaluated by comparing post-injection and pre-injection patient global assessment scores: feasibility was evaluated by observing if completed WOMAC questionnaires were accompanied by completed patient global assessment questions.

Results

Only 445 five patients received injections, since 29 of the 474 physicians were unable to supply a patient but had not stated this in the interview selection process (completion rate = 94%). Of the 890 potentially available WOMAC/PGA questionnaires, 602 were returned sometime after the first injection: of these, there were 163 complete pairs (i.e., preaccompanied by post) that were used in the analyses reported. Of the remainder, 115 had only a pre- and 25 only a post-injection assessment, 18 contained data from different knees at the two assessment points, and in 118 (59 pairs), the post-injection assessment was made less than 21 or more than 84 days after the pre-injection questionnaire was completed. Although all post-injection assessments should have been completed at 6 weeks, there was considerable variation in when post-injection assessments were made (Figure 1). We elected to restrict the data analysis to

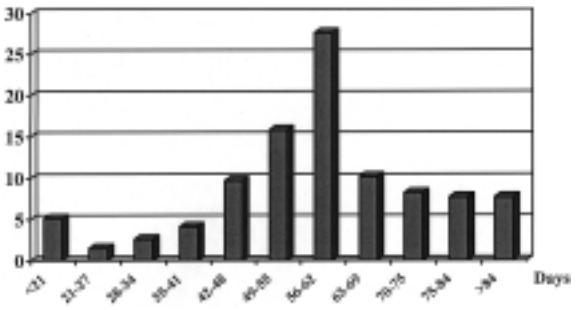

Figure 1 Time to completion of post-injection WOMAC 3.0.

subjects who had completed their post-injection assessments between 3 and 12 weeks. Three weeks is the first week after completion of the series of three injections, and 12 weeks is the point used in several published studies to evaluate the early response to Synvisc™.

Data from 163 subjects were used in the analysis. Pre- and post-injection WOMAC scores and associated change scores for the two subscales are presented in Table 1. These improvements were clinically important and statistically significant for both WOMAC 3.0 subscales (pain = physical function at $p < .001$, by both parametric and nonparametric analyses). Notwithstanding the current lack of responder criteria for osteoarthritis knee studies, patients were classed as responders if they fit either of the following two definitions: 20% or more reduction in pain and 20% or more reduction in pain as well as 20% or more improvement in physical function. Seventy-four percent of participants were responders by the first definition and 73% by the second.

More than 94% of family practitioners agreed or strongly agreed that the VIP program was practical and relevant, met their objectives and expectations, was credible and well organized, that time and interaction were adequate, that the preceptor was knowledgeable, and that they now felt comfortable with the procedure and would consider viscosupplementation as a treatment option for osteoarthritis knee patients in their practice (Table 2). Almost 100% of preceptors agreed or strongly agreed that the program was practical and relevant, met their objectives and expectations, was credible and well organized, that time and interaction were adequate, and that they would participate in future VIP programs.

With respect to the validation of the patient global assessment question, there was a strong positive correlation between patient global assessment scores and WOMAC pain and function scores. For pre-injection, pain had an r = 0.59 and function had an r = 0.62 at $p < .001$; post-injection pain had an r = 0.79 and function had an r = 0.77 at $p < .001$; the change score for pain had an r = 0.69 and function, an r = 0.71 at $p < .001$.

Table 1 Clinical Profiles Pre- and Post-Injection with Synvisc™

	Variable	n	Mean	SD	Min.	Max.
Pre-injection	WOMAC pain	163	10.55	3.45	1	20
	WOMAC function	163	37.36	11.67	8	68
	Global assessment	157	2.94	0.79	1	4
Post-injection	WOMAC pain	161	6.04	4.5	0	20
	WOMAC function	163	23.18	14.36	0	66
	Global assessment	161	1.71	1.14	0	4
Pre- to post-difference	WOMAC pain	161	4.50*	4.16	–11	18
	WOMAC function	163	14.18*	14.32	–37.69	54
	Global assessment	156	1.21*	1.19	–3	4

* $p < .001$, by Student's *t*-test and Wilcoxon Signed Rank test.

Table 2 VIP Program Evaluation Summary

Ranking		Neutral (%)	Agree (%)	Strongly Agree (%)
Practice relevancy	EP	–	26.0	74.0
	FP	0.6	29.2	69.6
Met course objectives	EP	–	26.0	74.0
	FP	1.9	26.1	71.4
Met personal expectations	EP	–	32.0	68.0
	FP	2.5	27.5	69.4
Credible	EP	–	42.0	58.0
	FP	3.1	31.7	64.6
Well organized	EP	5.0	37.0	58.0
	FP	1.9	27.3	69.6
Adequate time for learning	EP	–	26.0	74.0
	FP	2.5	25.8	70.4
Adequate interaction with expert and peers	EP	–	21.0	79.0
	FP	0	20.1	78.6
Participate as expert again	EP	–	21.0	79.0
	FP	–	–	–
Learning objectives met	EP	–	–	–
	FP	0.6	25.0	73.7
Knowledgeable and skilled expert preceptor	EP	–	–	–
	FP	0.6	13.8	84.9
Comfortable with repeating procedure	EP	–	–	–
	FP	4.6	28.7	65.7
Will use viscosupplement in practice	EP	–	–	–
	FP	–	38.3	60.7

EP = expert preceptor, FP = family practitioner.

Pre-injection and post-injection patient global assessment scores and the associated change scores relating to responsiveness are illustrated in Table 1.

The improvements noted were clinically important and statistically significant ($p < .001$ by both parametric and nonparametric analyses). With respect to feasibility, all completed WOMAC questionnaires were accompanied by completed patient global assessment questions.

Discussion

The majority of previous CME studies have assessed the consequence of the CME intervention at the level of the motivation, knowledge, or intention to change behavior by the learner.[8–12] While these are useful endpoints from an educational standpoint, they leave unanswered the more important question of whether the CME program had a meaningful and beneficial impact on the health status of patients subsequently treated by those who participated. This tendency to measure more-proximal endpoints is understandable, since the measurement of clinical consequence is both complex and costly. Furthermore, it is difficult to directly attribute alterations in the health status of patients to the learning intervention: this may have deterred some previous investigators from pursuing the more important distal endpoints. Clearly, attendees at CME events are to some

extent self-selected by motivation, need, and ambition, and such individuals are not readily randomized by whether they do or do not attend the CME event.[13,14] Moreover, once attendees return to their practices, it is no longer possible to randomize their patients and examine differential effects of being treated by their own physician with versus without the recently acquired skill.[15–18]

In this study, not only the experience of the preceptors and learners but also the changing health status of those patients whom they treated immediately after acquiring the skills necessary to perform viscosupplementation were evaluated. The preceptors were clearly satisfied with the educational experience even prior to observing a beneficial effect on the patients they subsequently injected. It is noteworthy that, following review of the SAM and completion of a supervised injection of Synvisc™, almost all family practitioners felt comfortable about viscosupplementation and would consider its use in future management of osteoarthritis knee patients. For the family practitioners, this represented a relatively small time commitment to acquire a skill of general value in the management of osteoarthritis and delivery of intra-articular therapy. It also permitted skills acquisition to occur in a clinical environment supportive for both the family practitioner and participating patients. The preceptors were often teaching in locations remote from their practices and on patients they had not previously met or examined. That the preceptors were also satisfied with their involvement in the VIP programs and would participate in future programs underscores the success of the intervention.

This is particularly remarkable given the inherent difficulty of maintaining consistency in delivering a learning intervention at multiple sites in different geographic areas with regional variations in health care systems, and involving faculty and learners with different medical specialty backgrounds. The uniformly high level of satisfaction expressed by faculty and learners can be attributed to the planning, design, and delivery approaches employed in this intervention. Variations of several adult learning principles and other approaches described in the literature were adopted and applied,[19–21] and may be summarized as follows:

1. A multi-stakeholder approach, receiving input and validation by faculty and learners at each stage of the development and delivery processes;

2. Multiple learning devices versus reliance on a single educational event;

3. Delivery in or close to the community in which the learners practice;

4. Learners involving their own patients rather than artificial models;

5. Small learning groups; and

6. Self-assessment and immediate feedback to faculty and learners from their own observations of patient outcomes provided by their administration of the pre- and post-injection WOMAC 3.0 questionnaires.

In assessing patient outcomes, it is important to use measures that are valid, reliable, and responsive. The WOMAC osteoarthritis index is one such measure, and has been extensively used in over 50 countries throughout the world.[2,22,23] In this study, clinically important improvements were noted in WOMAC pain and function scores. Furthermore, while there is currently no internationally accepted definition of responder criteria for osteoarthritis knee studies, a cutpoint used in rheumatoid arthritis studies[24] was borrowed and three-quarters of patients were observed to experience a clinically meaningful response in both pain and function following viscosupplementation.

Furthermore, the patient global assessment question used in this study was shown to be valid, sensitive to change, and feasible, thus fulfilling the requirements of the OMERACT filter. It is therefore proposed that the patient global assessment

be used to supplement the standard WOMAC 3.0 index to create a WOMAC 4.0, or that it replaces the stiffness subscale in the WOMAC 3.0 to create a modified index termed the WOMBAT 3.0 that meets OMERACT/OARSI guidelines.

Potential limitations of the study merit consideration. In general, bias may occur as control over experimental conditions diminishes. Clinical benefit was observed among patients treated by participants in the VIP program. Since the program was delivered as a package, the relative contribution of its different components cannot be discerned. However, the combination of the SAM and the experienced preceptors provided optimum conditions for small-group learning and for practicing a newly acquired skill. This was an open study in which expectation bias both by the family practitioner and patient could modulate the response, potentially in a favorable direction. For example, the family practitioner could have presented the possible benefits to patients in an enthusiastic way, and patients who elected to participate might be self-selected on that basis. However, double-blind randomized placebo-controlled trials of Synvisc™ have demonstrated the intrinsic efficacy of viscosupplementation,[25] which has been substantiated in controlled trials of nonsteroidal class agents[26] as well as in open studies,[27] indicating that while the response may be modulated by expectation in some patients, it does not account for the improvement in health status observed.

Some procedures required for this study were more commonly used in clinical trials based in academic centers. The requirements for patient selection were detailed in the SAM, while the verification of a diagnosis of knee osteoarthritis was performed by the expert preceptor based on a personal interview and examination of the knee and accompanying radiographs. Of the 445 patients who participated, complete WOMAC/patient global assessment data within the 3- to 12-week period were available on 163, although some data were available on 380 patients. These protocol violations and losses to follow-up are likely attributable to the absence of a clinical research organization monitoring the data acquisition, a contingency strongly recommended for future family practitioner-based studies of this type.

The use of a self-administered outcome measure (WOMAC 3.0) in this study obviated any family practitioner-associated positive reporting. While the global question in the WOMBAT is new, this question is valid, responsive, and feasible, and may be used in future osteoarthritis knee studies either within the WOMBAT 3.0 or as a supplementary question within a WOMAC 4.0 index.

Conclusion

The VIP program was successful in training family practitioners to apply a safe and effective intra-articular therapy in patients with knee osteoarthritis. The most important design element was longitudinal evaluation of those patients who were recipients of a family practitioner's newly acquired skill. The clinically important and statistically significant improvements in health status that occurred following Synvisc™ injection underscore the true value of the VIP program and establish a link between improved patient outcomes and a newly acquired learner skill when CME professionals apply several essentials of adult learning theory and incorporate a standardized validated health-status measure in design and delivery of a CME enterprise. In an environment of multi-stakeholder demand for evidence of effective use of health care resources, including CME resources, the use of patient outcomes as a measure cannot be ignored. CME professionals need to consider this trend and examine cost-effective ways of incorporating these measures into the design and delivery of future CME endeavors.

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