Nurse-Led Care for Stable Patients with Rheumatoid Arthritis: Quality of Care in Routine Practice Compared to the Traditional Rheumatologist-Led Model

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ABSTRACT

Introduction: This pragmatic non-inferiority study assessed quality of care within a nurse-led care (NLC) model for stable patients with rheumatoid arthritis (RA) compared to the traditional rheumatologist-led care (RLC) model.

Methods: Data were collected through a chart review. Baseline demographic and clinical characteristics were compared using Chi-square test and t test. The primary outcome measure was the percentage of patients being in remission or low disease activity (R/LDA) with the Disease Activity Score (DAS-28) ≤ 3.2 at 1-year follow-up. Process measures included the

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percentages of patients with chart documentation of (1) comorbidity screening; (2) education on flare management, and (3) vaccinations screening. Outcomes were summarized using descriptive statistics.

Results: Each group included 124 patients. At baseline, demographic and clinical characteristics were comparable between the groups for most variables. Exceptions were the median (Q1, Q3) Health Assessment Questionnaire Disability Index scores [0 (0, 0.25) in NLC and 0.38 (0, 0.88) in RLC, $p = 0.01$], and treatment patterns with 3% of NLC and 38% of RLC patients receiving a biologic agent, $p = 0.01$. NLC was non-inferior to RLC with 97% of NLC and 92% of RLC patients being in R/LDA at 1-year follow-up. Patients in the NLC group had better documentation across all process measures.

Conclusions: This study provided real-world evidence that the evaluated NLC model providing protocolized follow-up care for stable patients with RA is effective to address patients' needs for ongoing disease monitoring, chronic disease management, education, and support.

Key Summary Points

New models of care for stable patients with inflammatory arthritis are proposed as a solution to the challenges of scarce rheumatology healthcare resources.

This study provided real-world evidence that nurse-led care was at least as effective as rheumatologist-led care.

Nurse-led care was also associated with higher documentation of comorbidities screening, education about flares management, and vaccination screening.

Overall, a nurse-led care model where registered nurses provide protocolized follow-up care for stable patients with rheumatoid arthritis represents an effective strategy of addressing the patients' needs for ongoing disease monitoring, chronic disease management, education, and support.

INTRODUCTION

Rheumatoid arthritis (RA) is a chronic debilitating disease that affects 0.5–1.0% of the population worldwide [1, 2]. There are high rates of comorbid conditions in RA including cardiovascular diseases, pulmonary diseases, diabetes, osteoporosis, and depression; all contributing to substantial patient complexity [3, 4]. For optimal outcomes, patients with RA require timely diagnosis and therapy, and life-long specialty care [5–7]. Without continuous rheumatology follow-up, quality of care for patients with RA may decrease, as evidenced by the suboptimal use of conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) [8, 9]. Thus, regular follow-up with a rheumatologist is the current gold standard of care for patients with RA [5–7]. Nonetheless, the capacity of rheumatology care in many regions is insufficient to provide ongoing continuous specialty

Table 1 Comparison of models of care in the NLC and RLC groups [35]

	NLC group	RLC group
1. Rationale for the model's implementation	Shortage of rheumatologists [11]	A traditional historically emerged model of care
	FU of stable patients absorbs rheumatologists' care capacity [36], limiting their ability to accept new and urgent patients in a timely manner	
	Increased complexity of patients due to comorbidities and need for chronic disease management [3, 4]	
2. Goals of the model's development and implementation	Provide equivalent FU care and disease monitoring for stable patients as compared to traditional RLC	Provide FU care and disease monitoring for stable patients
	Provide comorbidity screening and lifestyle counseling for stable patients	
	Increase capacity for rheumatology care	
3. Model's development	Developed by a rheumatologist and 2 RNs at site A	A traditional historically emerged model of care
	Development included:	
	Practice audit to identify eligible patients	
	Defining the process (i.e., booking process, clinic conduct, data capture, communication)	
	Development of the infrastructure (i.e., booking system, for ongoing patient care, EMR, educational and communication materials)	
4. Model's implementation	Negotiation of funding	A traditional historically emerged model of care
	Training of staff	
	Identification and recruitment of patients	
	Established in April 2014	

Table 1 continued

	NLC group	RLC group
5. Rheumatology staff	2 FTE rheumatologists	8 FTE rheumatologists
	2 FTE RNs	0.4 FTE nurse-practitioner
	1 FTE LPN	3.8 FTE RNs
	3 FTE clerks	1.8 FTE licensed practice nurses
	0.5 FTE pharmacist	5 FTE clerks
		0.8 physiotherapist
		0.5 FTE pharmacist
6. Nurses' experience prior to the model's implementation	RNs	Experience varied
	Over 10 years of experience in rheumatology	
7. Nurses' training during the model's implementation	A year-long training was incorporated in the regular work of the team	Not applicable
	Nurses were mentored by the rheumatologist and participated in clinics under rheumatologist supervision to learn and practice:	
	Assessment and interpretation of disease activity using the DAS-28 tool	
	Interpretation of relevant laboratory tests	
	Recognition of situations when changes in therapy are needed	
	Assessment of important comorbidities and understanding of relevant medications	
	Advanced Rheumatology Course [37]	
8. Continuing training for nurses after the model's implementation	Weekly rheumatology rounds and yearly workshops for Allied Health Care providers	Some nurses attended an advanced training for Allied Health Care providers

Table 1 continued

	NLC group	RLC group
9. Providers involved in care for stable patients	Rheumatologist	Rheumatologist
	RN	May also include:
	LPN	RN
	Other healthcare professionals (e.g., pharmacist, social worker) are available upon request as required	LPN
		Other healthcare professionals (e.g., pharmacist, physiotherapist, social workers) are available upon request as required
10. Rheumatologist's roles	A rheumatologist would see each patient in the NLC group. At the end of the visit with a nurse, a rheumatologist would spend about 5 min with the patient and the nurse, unless due to any more time is required	Examining patient
	Reviewing disease status with the nurse	Adjusting therapy if needed
	Addressing nurse's and patient's questions if needed	Providing prescriptions
	Providing prescriptions	Communicating with PCPs through letters
	Examining the patient, adjusting therapy, and leading patient FU if required (e.g., patient's disease is not stable, increased level of patient's complexity due to comorbidities, pregnancy, and other reasons)	Providing referrals to other healthcare providers and/or medication classes if needed

Table 1 continued

	NLC group	RLC group
11. Nurse's roles	During patient's visit:	Nurses may assist rheumatologist during FU visits as needed
	Recording details in EMR	Roles may include:
	Reviewing the state of the rheumatic disease and other medical issues over the past year	Recording of patient vitals
	Reviewing medications and side effects	Patient education
	Reviewing laboratory testing results, frequency of and adherence to laboratory testing	Assessment of patient
	Examining patient including 66 swollen and tender joint count,	Assistance with procedures
	Reviewing HAQ-DI scores and discussing results with the patient,	Assistance with obtaining coverage for medication
	Calculating DAS-28	
	Assessing CVD disease risk by calculating Framingham score [38]	
	If appropriate, assessing the risk of osteoporosis by calculating FRAX score [39]	
	Assessing patient's lifestyle (e.g., physical activity, diet, emotional well-being, and smoking status)	
	If needed, advising on smoking cessation	
	Assessing vaccination status and advising on benefits of vaccinations	
	Providing education about the disease, flares, and self-management using a standardized brochure developed by the site A team	
	Providing education about the increased risk of comorbidities associated with RA through standardized brochures, discussions with patients, and recommendations to visit a PCP for ongoing risk assessment and management	
	Reviewing patient status with the rheumatologist	
	Ensuring renewal of prescriptions and laboratory test requisitions	
	Communicating with PCPs using standardized reporting letter generated from the data collection form	
	Providing referrals to other healthcare providers and/or medication classes if needed	
	Providing phone consultation between visits if needed	

Table 1 continued

	NLC group	RLC group
12. LPN's role	Recording patient vitals	Same as nurses but do not do a patient assessment
	Supporting flow of concurrent clinics	
13. Patients' role	Self-management between visits	Self-management between visits
	Contacting clinic in case of a flare	
14. Frequency of FU	Every 12 months for stable patients	FU intervals for stable patients are at the discretion of the treating rheumatologist, commonly every 6 to 12 months
	In between visits, patients have access to phone advice from nurses if needed	In between visits, patient concerns are directed through the rheumatologists' office or directed to nurses working in biologics clinics for those patients who are treated with a biologic agent
	FU intervals in case of active disease are at the discretion of the treating rheumatologist	FU intervals in case of active disease are at the discretion of the treating rheumatologist
15. Duration of FU visit	30 min unless unstable	15–20 min unless unstable
16. Data collection	Standardized data collection form through EMR developed by the rheumatology team at site A	No standardized data collection approach
	EMR follows the protocol outlining steps and procedures for ongoing patient care used in the clinic	Paper charts and EMR are used based on rheumatologists' preferences
	EMR includes fields such as patient physical activity levels, screening for CVD disease and osteoporosis, vaccinations status, smoking status and smoking cessation counselling, patient's education and communication with PCPs	
	EMR is shared by all members of the rheumatology team to facilitate ongoing communication	
17. Communication with PCPs	Standardized reporting letter generated by the nurse from the EMR	Letters with no standardized reporting
	Letters are reviewed by the rheumatologist	Letters are written and sent by the rheumatologist
	Finalized letters are sent by the nurse	

Table 1 continued

	NLC group	RLC group
18. Logistics of the model	During the visits, nurses follow a protocol outlining steps and procedures for ongoing patient care	Not applicable
	Both RNs at site A lead NLC clinics	
	Only 1 NLC clinic is run at a time due to nurses' participation in concurrent clinics	
	NLC clinics are held simultaneously with RLC clinics to ensure rheumatologist's availability	

CVD cardiovascular disease, *DAS-28* Disease Activity Score-28, *EMR* electronic medical record, *FU* follow-up, *FTE* full-time equivalent, *HAQ-DI* Health Assessment Questionnaire Disability Index, *LPN* licensed practice nurse, *NLC* nurse-led care, *PCP* primary care provider, *RN* registered nurse, *RLC* rheumatologist-led care

care for established patients and timely access to care for new and urgent patients [10, 11].

Innovative models of care delivery have the potential to increase rheumatology care capacity as well as improve the quality of patients' care [12]. Shared care is one example of an innovative model. In shared care, non-physician care providers and/or general medicine physicians with an extended scope of practice work in an alternative role to provide regular patient follow-up in lieu of specialists [13–15]. Besides, they may work in a complementary role to provide additional healthcare services (e.g., screening for comorbidities, psychological support, lifestyle management, and supporting patients in the development of skills and confidence for self-management) [13–15]. For instance, shared care models led by nurses, nurse-led care (NLC), for the follow-up of patients with RA were shown to be at least as effective, safe, and acceptable to patients as compared to rheumatologist-led care (RLC) follow-up [12, 13, 16, 17]. However, the full range of effects of NLC models on quality of care for patients with RA has yet to be explored [13]. Similar to other complex health interventions, NLC affects multiple dimensions of quality of care [13] with some outcomes (e.g., patient knowledge, confidence for self-management, and satisfaction with care) being more difficult to measure [15, 18]. Research is needed to assess complex effects on the quality of care associated with both alternative and complementary aspects of NLC [15].

This study aimed to assess the quality of care within a collaborative NLC model for stable patients with RA compared to the traditional RLC model using a structured evaluation framework with outcome and process quality measures.

METHODS

This was a non-inferiority retrospective cohort study at two separate urban rheumatology clinical sites within a single academic center in Alberta, Canada, with a catchment area with over 1,500,000 people. There are approximately 3,500 and 14,000 patient visits per year at site A and site B, respectively. Both sites offer general

Table 2 Summary of the assessed clinical characteristics and quality measures

Quality measures		Details
Full description	**Abbreviated title[a]**	
Primary outcome measure		
Patients in R/LDA at 1-year FU visit	Patients in R/LDA at 1-year FU	Patients who did not have a 1-year FU visit and/or their DAS-28 was not reported or could not be calculated were excluded
Secondary outcome measure		
Visits where patients were in R/LDA	Visits with R/LDA	Visits where DAS-28 was not reported or could not be calculated were excluded
Clinical characteristics		
HAQ-DI at 1-year FU visit	HAQ-DI at 1-year FU	Patients who did not have a 1-year FU visit and/or their HAQ-DI score was not reported or could not be calculated were excluded
DAS-28 at 1-year FU visit	DAS-28 at 1-year FU	See details on 'Patients in R/LDA at 1-year FU'
Process measures		
Visits where patients were not in R/LDA with a change in medications made at that visit	Not-R/LDA visits with a change in medications	See details on 'Visits where patients were in R/LDA'
Days to rheumatologist assessment after contacting the rheumatology team about the disease flare	Days to assessment after flare	Patients who had an explicit record when they contacted the rheumatology team about the flare were included
Patients with gaps in care of > 12 months between 2 consecutive visits	Gaps in care > 12 months	
Patients with gaps in care of > 14 months between 2 consecutive visits	Gaps in care > 14 months	
Patients with at least 1 chart documentation on the education about RA flares and when to contact the clinic in case of a flare	RA flares education	Patients with explicit records of patients' education about RA flares (e.g., 'information on RA flares and contacting the clinic was provided', 'patent was advised when to contact the clinic in case of a flare') were included in the numerator
Patients with at least 1 chart documentation on the rheumatology team's communication of the associated with RA increased CVD risk to the PCP	CVD risk communicated to PCP	Patients with explicit records of the rheumatology team's communication of the associated with RA increased CVD risk to the PCP (e.g., 'RA is associated with increased CVD risk') were included in the numerator
Patients with at least 1 chart documentation on their smoking and tobacco use status	Smoking and tobacco use status	Patients with a documented lifelong non-smoker and ex-smoker status before or at the baseline visit were excluded

Table 2 continued

Quality measures		Details
Full description	**Abbreviated title[a]**	
Patients who were current smokers or tobacco users with at least 1 chart documentation on the smoking cessation counseling done by the rheumatology team, %	Smoking cessation counseling, %	Patients with explicit records of the smoking cessation counselling (e.g., "Patient was advised about smoking cessation", "Patient is not interested in smoking cessation") were included in the numerator
Visits with BP measured and documented in the medical chart, %	BP documented, %	Visits of patients with a lower recommended threshold due to diabetes or chronic kidney disease were excluded
Patients whose BP was measured and documented in the medical record at ≥ 80% of clinic visits, %	BP documented at ≥ 80% of visits, %	See details on 'BP documented'
Patients > 50 years with at least 1 chart documentation on the education about the associated with RA increased risk of osteoporosis and/or fractures	Education about osteoporosis and/or fractures	Patients with explicit recording of patients' education about osteoporosis and/or fractures, their diagnosis and/or treatment (e.g., "risk of osteoporosis and/or fractures was discussed with the patient", "patient was advised to have their bone density scan done", "benefits of calcium and vitamin D were discussed") were included in the numerator
Patients with at least 1 chart documentation discussing benefits of vaccinations	Benefits of vaccinations discussed	Patients with explicit records of the vaccination status and/or patient's education about vaccinations (e.g., 'patient received annual flu vaccine", "patient refuses to be vaccinated", "benefits of vaccination were discussed", "patient was advised to get a flu shot") were included in the numerator
Patients with at least 1 chart documentation about being vaccinated with an influenza vaccine	Patients vaccinated with an influenza vaccine	Patients with explicit records of vaccination status with an influenza vaccine were included in the numerator
Patients treated with hydroxychloroquine with at least 1 chart documentation on reminders for ophthalmologist yearly FU	Ophthalmology FU reminders	Patients with explicit records of ophthalmologist FU and/or the rheumatology team's reminder to book an appointment with an ophthalmologist (e.g., "the patient saw an ophthalmologist a month ago", "the patient was reminded to book a FU appointment with an ophthalmologist") were included in the numerator

BP blood pressure, *CVD* cardiovascular disease, *DAS-28* disease activity score-28, *FU* follow-up, *HAQ-DI* Health Assessment Questionnaire Disability Index, *%* percentage, *PCP* primary care provider, *R/LDA* remission or low disease activity, *RA* rheumatoid arthritis
[a] Abbreviated titles were used in Table 4

rheumatology clinics as well as sub-speciality clinics. At site A, stable patients with inflammatory arthritis have a choice to be followed by nurses in NLC clinics, which are offered once or twice a week.

Models of Care Delivery

The groups of patients included in the study were cared for in two models of care delivery— NLC (site A) and RLC (site B). Characteristics of the models of care are shown in Table 1.

In the NLC model, registered nurses act in an alternative role to monitor patients' disease activity in lieu of a rheumatologist; and in complementary roles to provide patients comorbidity screening and education, as well as to support standardized clinic documentation and communication with primary care providers (PCPs). During patients' visits, nurses follow a protocol outlining steps and procedures for ongoing care. The protocol includes a review of the patient's rheumatic disease and other health conditions over the last year; wellness and lifestyle assessment; rheumatic disease activity assessment; patient education; and, if appropriate, comorbidity screening. Next, a rheumatologist reviews the patient's arthritis status with the nurse, examines the patient if indicated, and renews prescriptions. If the patient's disease is not well controlled, the rheumatologist adjusts treatment as needed and the next appointment would be scheduled in the RLC model. Patients return to the NLC again if they remain stable for at least 6 months. Visit results are recorded in a standardized electronic medical record (EMR) and communicated to the patient's PCP. In between yearly visits, patients have access to phone advice from nurses if needed. In case of a flare, patients are advised to call the clinic and arrange an appointment with a rheumatologist.

Patients in the RLC group were cared for by their rheumatologists at site B. At site B, nursing roles in the follow-up stable patients are not protocolized and vary based on the needs of rheumatologists and availability of staff during clinics. Site B also offers education classes on arthritis, the associated risk of comorbidities, and wellness; however, no standardized protocols for comorbidity screening, patient education, or lifestyle assessment during follow-up visits for stable patients are available. At site B, patient concerns were directed through the rheumatologists' office.

Patient Population

At site A, patients who would be eligible for the NLC were identified by their treating rheumatologist. Patients were considered to be eligible if they: (1) had no more than 1 visit to the rheumatologist during the previous year; (2) were in remission or low disease activity (R/LDA) according to Disease Activity Score-28 (DAS-28) for at least 12 months; (3) did not require any changes in medications, and were not treated with oral corticosteroid therapy for RA during the previous visit; (4) did not have multiple unmanaged comorbidities or dementia, and (5) were not pregnant or planning a pregnancy (Supplementary Material). For eligible consenting patients, their next appointments were scheduled in the NLC.

In the present study, the first 124 consecutive patients with RA that (1) were seen in the NLC after April 1, 2014; (2) agreed to continue follow-up in the NLC; (3) were in R/LDA according to DAS-28 at the first visit in the NLC; (4) were not pregnant or planning a pregnancy; and (5) did not move over the follow-up time were included in the analysis.

Patients with RA under RLC at site B were retrospectively identified by applying the criteria used to identify patients eligible for the NLC at site A. First, rosters of patients of two experienced rheumatologists at site B were reviewed. These rheumatologists were selected as they were expected to have a similar mix of patients as the rheumatologist who designed the NLC at site A. Scheduling data were used to identify patients who had no more than one visit to the rheumatologist every 6 months between October 1, 2012 and March 31, 2014 (Supplementary Material). Next, clinical charts of the identified patients were screened to confirm the diagnosis of RA and to ascertain clinical stability at rheumatology visits 1 year before and at the first

Table 3 Baseline demographic and clinical characteristics for patients in the NLC and RLC care groups and csDMARDs subgroups

Characteristics	NLC, N = 124[a]	RLC, N = 124[a]	p	NLC csDMARD, N = 119[a]	RLC csDMARD, N = 76[a]	p
Age, years, mean (SD)	60 (13)	61 (14)	0.51	60 (13)	62 (14)	0.35
Female	87 (70)	83 (67)	0.58	84 (70)	50 (65)	0.46
Disease duration since diagnosis, years, median (Q1, Q3)	6 (3, 10), N = 123	6 (4, 15), N = 110	0.56	6 (3, 10), N = 118	5 (3, 8), N = 68	0.22
HAQ-DI[b], median (Q1, Q3)	0 (0, 0.25), N = 122	0.38 (0, 0.88), N = 100	0.01	0 (0, 0.25), N = 117	0.31 (0, 0.82), N = 56	0.05
DAS-28, mean (SD)	1.77 (0.69), N = 117	1.91 (0.66), N = 76	0.18	1.77 (0.70), N = 114	1.84 (0.60), N = 46	0.49
Patients in remission	103 (88), N = 117	62 (82), N = 76	0.21	100 (88), N = 114	39 (85), N = 46	0.62
Patients in LDA	14 (22), N = 117	14 (28), N = 76	0.21	14 (12), N = 114	7 (15), N = 46	0.62
CRP, mean (SD)	3 (5), N = 34	5 (10), N = 41	0.51	3 (4), N = 33	3 (5), N = 28	0.95
ESR, mean (SD)	12 (11), N = 85	13 (15), N = 60	0.62	12 (11), N = 82	12 (16), N = 32	0.99
RA treatment						
Any csDMARD	123 (99)	103 (83)	0.01	119 (100)	76 (100)	n/a
HCQ	84 (68)	66 (53)	0.02	84 (71)	56 (74)	0.64
Methotrexate	112 (90)	85 (69)	0.01	108 (91)	63 (83)	0.10
Leflunomide	< 6 (< 5)	< 6 (< 5)	0.10	< 6 (< 5)	0	0.07
Sulfasalazine	< 6 (< 5)	18 (15)	0.01	< 6 (< 5)	13 (17)	0.01
Any combination csDMARD therapy	80 (65)	58 (47)	0.18	80 (67)	49 (65)	0.69
Methotrexate + HCQ	75 (61)	51 (41)	0.01	75 (63)	45 (59)	0.59
Biologics	< 6 (< 5)	47 (38)	0.01	n/a	n/a	n/a
No csDMARD or biologics	< 6 (< 5)	< 6 (< 5)	n/a	n/a	n/a	n/a
Intramuscular or intraarticular glucocorticoids	< 6 (< 5)	< 6 (< 5)	0.65	0	< 6 (< 8)	0.21
Comorbidities and their risk factors[b]						
CVD[d]	9 (7)	9 (7)	n/a	9 (8)	8 (11)	0.47
Stroke	< 6 (< 5)	< 6 (< 5)	0.65	< 6 (< 5)	< 6 (< 8)	0.33

Table 3 continued

Characteristics	NLC, $N = 124^a$	RLC, $N = 124^a$	p	NLC csDMARD, $N = 119^a$	RLC csDMARD, $N = 76^a$	p
Hypertension	32 (28), $N = 114$	39 (33), $N = 120$	0.46	31 (28), $N = 110$	25 (34), $N = 74$	0.42
Diabetes	9 (7)	< 6 (< 5)	0.15	7 (6)	< 6 (< 8)	0.55
Dyslipidemia	20 (16), $N = 123$	18 (15), $N = 122$	0.75	18 (15), $N = 118$	14 (18), N = 77	0.56
Obesity (BMI $\geq$ 30 kg/m^2)	37 (32), $N = 117$	26 (27), $N = 95$	0.50	35 (31), $N = 112$	16 (28), $N = 58$	0.62
Osteoporosis	< 6 (< 5)	12 (10)	0.01	< 6 (< 5)	6 (8)	0.01
Current smokers	19 (16), $N = 123$	< 6 (<11), $N = 55$	0.25	19 (16)	< 6 (< 16), $N = 38$	0.41

Values are n (%) unless otherwise specified

BMI body mass index, *CRP* C-reactive protein, *CVD* cardiovascular disease, *csDMARD* conventional synthetic disease-modifying anti-rheumatic drug, *DAS-28* disease activity score-28, *ESR* erythrocyte sedimentation rate, *Q1, Q3* first and third quartiles, *HAQ-DI* Health Assessment Questionnaire Disability Index, *HCQ* hydroxychloroquine, *LDA* low disease activity, *n/a* not applicable, *N* number, *NLC* nurse-led care, *p* p value, *%* percentage, *RA* rheumatoid arthritis, *RLC* rheumatologist-led care, *SD* standard deviation

[a] The numbers of patients included is as described at the top of the table, unless otherwise specified

[b] Comorbidities and their risk factors at baseline were deemed present at baseline if the condition was documented in the medical record or the patient was treated for the condition and were collected as 'yes', 'no', or 'unknown' if reviewers had major concerns about missing information in the chart

[c] CVD diseases included myocardial infarction, heart failure, atrial fibrillation, and other arrhythmias

clinical visit after January 1, 2014. If DAS-28 was not reported and could not be calculated, physician notes indicating that the patient was in R/LDA (e.g., "RA stable", "stable disease", "patient is doing well and no changes in medication required") were accepted as an indication of the stable disease. Patients who moved and ceased their follow-up at site B between their first clinical visit after January 1, 2014 and 1-year follow-up visit, as well as patients with multiple unmanaged comorbidities or dementia and pregnant patients, were excluded from the data extraction. The first 124 consecutive patients who met the inclusion criteria were selected for the comparator RLC group.

Duration of Follow-Up

For the NLC group, the first appointment in the NLC after the clinic's implementation in April, 2014, was used as the baseline visit. For the RLC group, the first clinical visit after January 1, 2014, was used as the baseline visit. In both groups, patients' follow-up continued until their 1-year follow-up visit. The 1-year follow-up visit was defined as a visit that occurred between 9 and 15 months after the baseline visit. If multiple visits occurred between 9 and 15 months after the baseline, the visit with a longer follow-up time was defined as the 1-year follow-up visit. If no visit occurred between 9

Table 4 Follow-up characteristics and quality measures assessment for patients in the NLC and RLC groups and csDMARDs subgroups

	NLC, N = 124[a]	RLC, N = 124[a]	NLC csDMARDs, N = 119[a]	RLC csDMARDs, N = 76[a]
FU per patient, days, mean (SD)	374 (25)	397 (46)	373 (26)	409 (44)
Visits over 100 days of FU per patient, mean (SD)	0.27 (0.03)	0.26 (0.02)	0.27 (0.02)	0.25 (0.03)
Clinical characteristics and outcome measures				
HAQ-DI at 1-year FU, median (Q1, Q3)	0 (0, 0.38), N = 117	0.44 (0, 1.13), N = 94	0.13 (0, 0.5), N = 114	0.5 (0, 1.13), N = 51
DAS-28 at 1-year FU, mean (SD)	1.72 (0.64), N = 113	1.93 (0.81), N = 73	1.70 (0.63), N = 110	1.94 (0.86), N = 40
Patients in R/LDA at 1-year FU	97 (109/113)	92 (67/73)	97 (107/110)	88 (35/40)
Patients who were stable at 1-year FU [b]	97 (115/119)	94 (99/105)	97 (112/115)	92 (55/60)
Patients in MDA at 1-year FU	4 (4/113)	8 (6/73)	3 (3/111)	13 (5/40)
Visits with R/LDA (7)	98 (234/239)	94 (186/198)	98 (228/232)	94 (106/113)
Visits when patients were stable[b]	94 (243/258)	91 (281/310)	95 (236/248)	92 (167/182)
Visits with MDA	2 (5/239)	6 (11/198)	2 (4/232)	6 (7/113)
Visits with HDA	0 (0/239)	1 (1/198)	0 (0/232)	0 (0/113)
Process measures				
Not-R/LDA visits with a change in medications	60 (3/5)	50 (6/12)	50 (2/4)	29 (2/7)
Days to assessment after flare, median (Q1, Q3)	10 (5, 17), N = 7	21 (n/a, n/a), N = 1	12 (6, 17), N = 6	n/a
Gaps in care > 12 months	60 (74/124)	17 (21/124)	61 (72/119)	20 (15/76)
Gaps in care > 14 months	2 (3/124)	6 (7/124)	3 (3/119)	8 (6/76)
RA flares education	98 (121/124)	2 (3/124)	98 (117/119)	0 (0/76)
CVD risk communicated to PCP	90 (112/124)	2 (4/124)	91 (108/119)	4 (3/76)
Smoking and tobacco use status	100 (19/19)	18 (13/74)	100 (19/19)	21 (9/42)
Smoking cessation counseling	84 (16/19)	80 (4/5)	84 (16/19)	75 (3/4)
BP documented	93 (239/258)	58 (182/315)	93 (229/247)	56 (105/186)
BP documented at ≥ 80% of visits	86 (98/114)	50 (60/120)	86 (96/111)	51 (37/73)
Education about osteoporosis and/or fractures	92 (88/96)	19 (19/101)	85 (78/92)	0 (0/60)
Benefits of vaccinations discussed	99 (123/124)	8 (10/124)	99 (118/119)	4 (3/76)

Table 4 continued

	NLC, $N = 124^a$	RLC, $N = 124^a$	NLC csDMARDs, $N = 119^a$	RLC csDMARDs, $N = 76^a$
Patients vaccinated with an influenza vaccine	54 (67/124)	2 (3/124)	55 (65/119)	1 (1/76)
Ophthalmology FU reminders	98 (83/85)	17 (12/69)	98 (83/85)	9 (11/57)

Values are % (N/D) unless otherwise specified

BP blood pressure, *CVD* cardiovascular disease, *csDMARD* conventional synthetic disease-modifying anti-rheumatic drug, *DAS-28* disease activity score-28, *Q1*, *Q3* first and third quartiles, *FU* follow-up, *HAQ-DI* Health Assessment Questionnaire Disability Index, *HDA* high disease activity, *LDA* low disease activity, *MDA* moderate disease activity, *n/a* not applicable, *N* number, *NLC* nurse-led care, % percentage (numerator/denominator), *PCP* primary care provider, *R/LDA* remission or low disease activity, *RA* rheumatoid arthritis, *RLC* rheumatologist-led care, *SD* standard deviation

[a] The numbers of patients included is as described at the top of the table, unless otherwise specified

[b] Based on the analysis where the rheumatology team's opinion about the patient's disease status informed imputations of missing DAS-28 data

and 15 months after the baseline visit, the data collection stopped at 15 months.

Data Sources and Abstraction

The EMR and paper charts, which included nurses' and rheumatologists' notes, letters to PCPs and other specialists, and laboratory test requests and results, were reviewed. Reviewers with clinical training [international medical graduates (EL, CDRJ) and a nurse (AML)] with previous experience in medical chart reviews abstracted the data. Data were collected using a standardized data abstraction form developed using REDCap electronic data capture tools hosted at the University of Calgary [19, 20]. Each chart was reviewed, and data were abstracted at least by two independent reviewers. Where there were differences in the double data entry, charts were reviewed again and, if needed, discussed with rheumatologists from sites A and B to resolve disagreements.

At baseline, data on disease duration and comorbidities were collected. Comorbidities were deemed present at baseline if the condition was documented in the medical record or the patient was treated for the condition. Data collected at each visit included appointment type; patient's clinical characteristics and laboratory results; medications; documentation about screening for comorbidities and their risk factors; communication with PCPs; and patient education.

Quality Measures Assessment

Quality measures were selected from national [21, 22] and provincial sets of outcomes for the evaluation of models of care for patients with inflammatory arthritis (Table 2).

To capture effects associated with alternative aspects of the evaluated NLC model, the percentage of patients in R/LDA at 1-year follow-up visit [22] and the percentage of clinic visits where patients were in R/LDA over the follow-up time were selected as the primary and secondary outcome measures, respectively. These outcome measures were identified as key effectiveness outcomes by a provincial arthritis working group tasked with evaluating models of care [23]. Disease activity was extracted from charts or measured with the DAS-28 (erythrocyte sedimentation rate or C-reactive protein (CRP)) depending on data availability. Remission was defined as DAS-28 $\leq$ 2.6, low disease activity (LDA) as DAS-28 $>$ 2.6 and $\leq$ 3.2, moderate disease activity (MDA) as DAS-
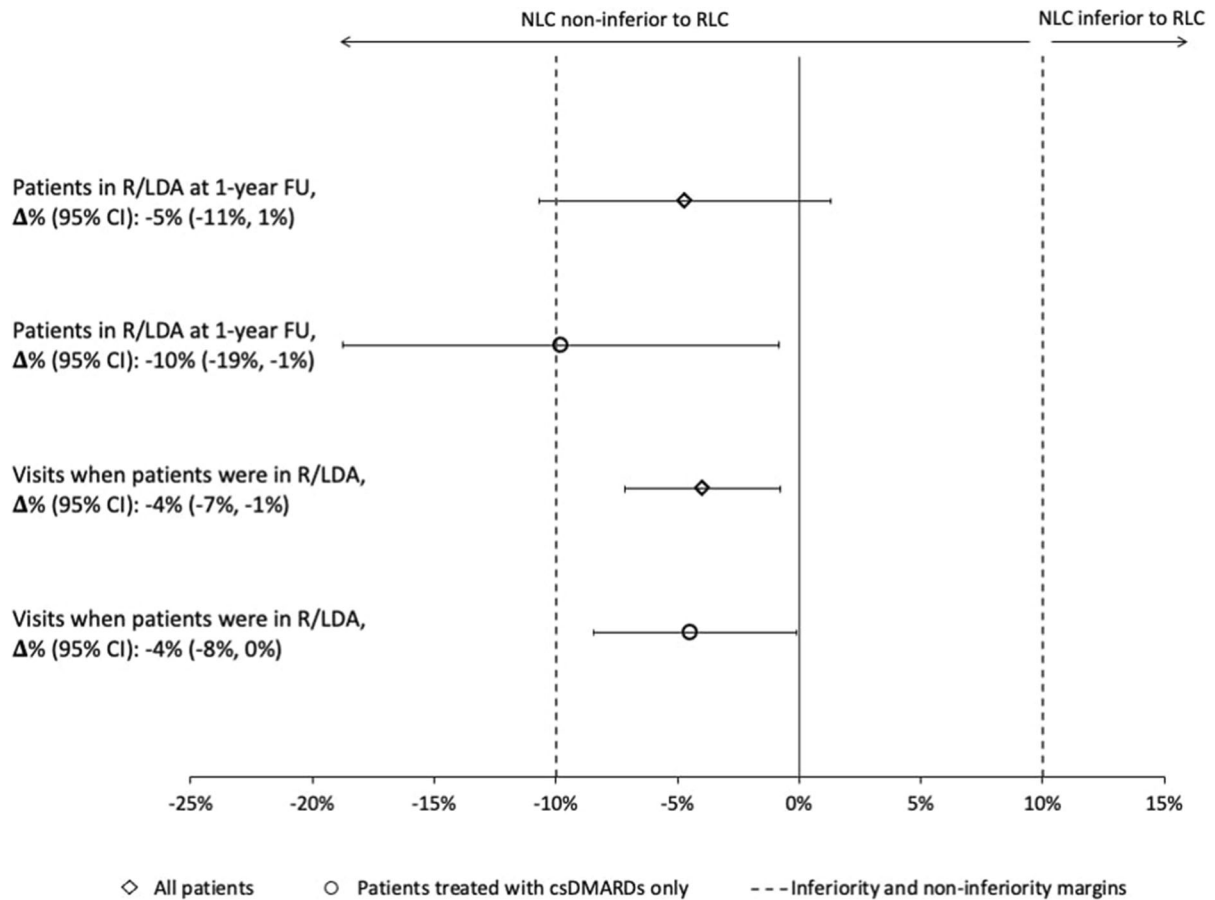
Fig. 1 Forest plot comparing primary and secondary effectiveness outcomes in the NLC and RLC groups and csDMARDs subgroups. *CI* confidence interval, *csDMARD* conventional synthetic disease-modifying anti-rheumatic drug, *FU* follow-up, *Δ%* mean difference in percentages between RLC and NLC, *NLC* nurse-led care, *%* percentage, *R/LDA* remission or low disease activity, *RLC* rheumatologist-led care

28 > 3.2 and ≤ 5.1, and high disease activity (HDA) as DAS-28 > 5.1.

To capture effects associated with complementary aspects of the evaluated NLC model, secondary process measures were used. They included percentages of patients with at least one chart documentation of (1) communication of the associated with RA increased cardiovascular risk to the PCP [21]; (2) smoking status [21]; (3) counseling current smokers or tobacco users to stop smoking [21]; (4) communicating the associated with RA increased risk of osteoporosis and fracture; (5); vaccination status with influenza and pneumococcal conjugate vaccines; (6) discussing benefits of vaccinations with the patient; (7); reminders for ophthalmologist yearly follow-up for patients treated with hydroxychloroquine; and (8) percentage of patients with blood pressure documented at ≥ 80% of clinic visits [21].

Sample Size Calculations

The sample size was calculated using a non-inferiority criterion for the primary outcome of the percentage of patients in R/LDA at 1-year follow-up. For both groups, the percentage 'successes' was assumed to be 90%. Assuming 10% non-inferiority margin, 80% power, and one-sided statistical testing with a 5% significance level, a minimum of 112 patients per group were required. To account for potentially

missing data, the sample size was increased by 10% with a total of 248 patients included.

Analysis

Descriptive statistics [i.e., proportions, means, and their standard deviation (SD) or medians with first and third quartiles (Q1, Q3)], depending on the normality of the data, were used to summarize baseline demographic characteristics, baseline and 1-year follow-up clinical characteristics, and quality measures over the follow-up. Cell sizes with less than 5 patients and/or visits were reported as <6. Baseline clinical characteristics for the NLC group patients who were excluded from the analysis due to active disease at the first visit were reported separately (Supplementary Material).

A sensitivity analysis was conducted to account for differences in treatment patterns in the NLC and RLC groups. In this analysis, the subgroups of patients treated with csDMARDs only were included, excluding patients on advanced therapies (i.e., biologic agents) and patients on no medications.

Baseline demographic and clinical characteristics were compared between the NLC and RLC groups and the csDMARDs subgroups using Chi-square test and *t* test as appropriate for the data. The hypothesis of non-inferiority of NLC compared to RLC in terms of the effectiveness was tested using one-sided 95% confidence intervals (CIs) of the mean differences in the primary and secondary outcomes between the RLC and NLC groups and between the csDMARDs subgroups [24].

In case of missing data, patients and/or visits were excluded from the analysis (Table 2). For the primary and secondary outcome measures, an additional analysis where the rheumatology team's opinion about the patient's disease status informed imputations of missing disease activity data. In this analysis, patients with missing DAS-28 data were considered to be stable during the visit if there was a note indicating that the patient was stable (i.e., "RA stable", "Disease under control", "The patient is doing well and no changes in medications are

required") and were considered to be not-stable is the note indicated that (i.e., "RA active", "Flare", "RA is not under control").

Ethics and Consent

This study was performed in accordance with the Helsinki Declaration of 1964 and its later amendments. The project was approved by the University of Calgary Health Research Ethics Board (REB17-1678). The approval included a waiver of patient consent for this research and publication due to the limited feasibility of obtaining patients' consents for the collection and analysis of retrospective data and the publication of results as well as the minimal risks or discomforts associated with the research.

RESULTS

Baseline and Follow-Up Characteristics

A total of 477 charts were screened and 248 patients (124 in the NLC group and 124 in the RLC group) were included in this study (Supplementary Material).

The mean age of patients included was 60.6 years and 68.6% were female (Table 3). At baseline, patients in the NLC and RLC were comparable in terms of their clinical characteristics. The median (Q1, Q3) disease duration since diagnosis was 5.9 (2.6, 9.8) years and 6.1 (3.8, 14.5) years and the mean (SD) DAS-28 was 1.76 (0.69) and 1.89 (0.65) in the NLC and RLC groups, respectively. The NLC group had a lower median (Q1, Q3) baseline health assessment questionnaire disability index (HAQ-DI) score (0 (0, 0.25) than the RLC group (0.38 (0, 0.88); $p = 0.01$). The groups also differed in terms of their baseline treatments with 3% of NLC and 38% of RLC patients receiving a biologic agent, $p = 0.01$. In the sensitivity analysis, the csDMARDs subgroups were comparable in all baseline clinical characteristics. The median (Q1, Q3) baseline HAQ-DI scores were 0 (0, 0.25) and 0.31 (0, 0.82) in the NLC and RLC subgroups, respectively; $p = 0.05$.

The observed mean (SD) changes in DAS-28 scores between baseline and 1-year follow-up were 0.12 (0.66) in the NLC group and 0.21 (0.75) in the RLC group. The mean (SD) changes in HAQ-DI were - 0.17 (1.26) in the NLC group and 0.05 (0.39) in the RLC group. These changes were below thresholds reported in the literature for minimal clinically important changes of 1.2 for deterioration in DAS-28-CRP and − 0.38 for improvement in HAQ-DI [25, 26]. In the sensitivity analysis, there were no clinically significant differences in the observed changes in DAS-28 and HAQ-DI scores between baseline and the 1-year follow-up in either csDMARD subgroup.

Quality Measures Assessment

DAS-28 scores were available or could be calculated to assess the primary outcome measure in 92% of NLC patients and 59% of RLC patients (Table 4). Overall, five NLC and 12 RLC patients were not in R/LDA during at least one visit over the follow-up time. Out of those, 16 patients were in MDA and one RLC patient was in HDA during one follow-up visit. The mean (SD) number of visits over 100 days of follow-up was 0.27 (0.03) and 0.26 (0.02) per patient in the NLC and RLC groups, respectively (Table 4). For patients who were not in remission or low disease activity during at least one visit over the follow-up time, the mean (SD) number of visits over 100 days of follow-up was 0.71 (0.29) in the NLC group and 0.81 (0.22) in the RLC group.

Patients were in R/LDA during the majority of visits with 97% of NLC patients and 92% of RLC patients being in R/LDA at the 1-year follow-up (Table 4). The mean difference (95% CI) in DAS-28 between NLC and RLC groups at 1-year follow-up was 0.21 (− 0.39, − 0.03). In the sensitivity analysis, 97% of NLC patients and 88% of RLC patients were in R/LDA at the 1-year follow-up. Overall, NLC was non-inferior to RLC with respect to the effectiveness of care when considering all included patients and the csDMARDs subgroups only (Fig. 1). In the analysis where missing DAS-28 data were imputed based on the rheumatology team's opinion about the patient's disease status, similar results were observed (Table 4).

Records of patients followed in the NLC model more commonly reported on comorbidities screening and documented patient education compared to the records of patients in the RLC group (Table 4). The groups were most alike in the chart documentation on smoking cessation counseling for current smokers or tobacco users with 84% of NLC and 80% of RLC eligible charts having corresponding documentation. However, differences in other process measures were observed between the groups. For example, over 90% of the NLC charts included documentation on the provided patient education about RA flares and when to contact the clinic in case of a flare, communication to the PCP of the increased cardiovascular risk associated with RA, and patient education about benefits of vaccinations at least once over the follow-up time. In the RLC groups, up to 8% of charts included documentation on these outcomes.

DISCUSSION

This non-inferiority study evaluated the quality of care for stable patients with RA in a collaborative NLC model compared to the traditional RLC model using a structured evaluation framework. Overall, NLC was at least as effective as RLC with better documentation of comorbidity screening and provision of patient education.

Our results support findings of previous evaluations and extend them in the context of real-life routine practice conditions, thus, focusing on the 'real-world' effectiveness of NLC models. Consistent with our findings, previous evaluations of NLC models for stable patients with RA [27–29] showed that NLC was non-inferior to RLC with mean differences in DAS-28 (95% CI) between the groups of − 0.21 (− 0.53, 0.11) and 0.04 (− 0.19, 0.27) at 12 months [27, 28]. These results were obtained in randomized control trials showing the efficacy of NLC models under ideal conditions rather than their effectiveness in routine clinical practice.

Furthermore, our evaluation included an assessment of process measures to capture effects associated with complementary aspects of the evaluated NLC model. Few published up-to-date qualitative and mixed-methods studies reported that nurses more frequently provided psychosocial support, education about the disease, and screening of comorbidities compared to RLC as perceived by patients and/or members of the rheumatology team [29, 30]. Consistent with these perceptions, higher rates of documentation of comorbidities screening, patients' education, and wellness assessment were observed in the NLC group across all process measures assessed in our study. Given the reported gaps in addressing the complex needs of patients with RA [21], NLC may present a potential solution to improving the quality of patients' care.

Findings of this study should be considered in the context of the strengths and limitations of the data. The documentation of clinical encounters varied between the groups. In the NLC group, a standardized EMR was used. In the RLC, no standardized data entry was used. Standardized EMRs have the potential to improve the quality of care and its documentation when used in a "meaningful" way [31]. Overall, records of patients in the NLC tended to be more complete in terms of clinical characteristics of patients and processes of care. Comorbidities screening and patient education may have taken place in the RLC group but was less consistently documented. Moreover, due to missing data, the final sample available for the analysis of some outcomes was less than required based on sample size calculations. Nonetheless, results of the additional analysis where the rheumatology team's opinion about the patient's disease status informed imputations of missing disease activity data, were consistent with the complete case analyses.

Amongst other limitations, the retrospective and non-randomized nature of this study should be discussed. Overall, given the retrospective nature of the study, outcomes of this evaluation were limited by the data available. The evaluation was limited to outcome and process measures within dimensions of the effectiveness and appropriateness of care and

did not assess patients' experience with care. Nonetheless, an overall high patients' satisfaction with the evaluated nurse-led clinic was previously reported [32].

To identify the comparator group from site B we applied the criteria used to identify eligible patients for NLC at site A. Yet, more patients in the RLC group were treated with biologics agents compared to the NLC group. In the evaluated NLC model, eligible patients were selected based on their disease activity status, and biologic treatment was not an exclusion criterion. However, before the establishment of the evaluated NLC, at site A, some stable patients with inflammatory arthritis treated with biologic agents were already cared for in a nurse-led biologic clinic. This could potentially lead to the observed difference in treatment patterns between the groups. Nonetheless, both groups were selected based on their disease activity status and, as expected, baseline DAS-28 scores were comparable between the NLC and RLC groups ($p = 0.21$). While our study did not aim to compare NLC in patients treated with csDMARDs versus patients treated with biologic agents, results of the sensitivity analysis with csDMARDs subgroups were consistent with the main analysis. These findings suggest that stable disease status rather than the treatment strategy could be a defining factor for identifying patients eligible for the NLC follow-up.

Furthermore, the difference in baseline functional status measure, HAQ-DI, between the groups was statistically significant. Higher HAQ-DI scores in the RLC group could be driven by the inclusion of a larger proportion of patients treated with biologic agents, which could be used more frequently in more severe cases of RA. In the sensitivity analysis, baseline HAQ-DI scores were not statistically significantly different between the csDMARDs subgroups. This could potentially reflect the complexity of clinical decision-making when identifying patients eligible for the nurse-led follow-up, which may be based on the whole picture of the patient's status known to their treating physician rather than the predefined selection criteria. Nonetheless, median baseline HAQ-DI scores in both groups were in the normal to mild functional loss range [33].

Additionally, in NLC, it is common practice for nurses to discuss HAQ-DI scores with patients to better differentiate between functional impairment caused by RA versus other comorbidities. If during the conversation, it was determined that the HAQ-DI score was not reflective of RA-related functional impairments, the questionnaire was revised with patient input. Therefore, lower HAQ-DI scores in the NLC group could also be driven by the education provided by nurses.

Lastly, at site A, only consented patients joined the NLC; and only patients who continued their follow-up in the NLC were included in the NLC group. This could potentially introduce a bias due to confounding as patient individual characteristics may influence their preferences for the type of follow-up care [34]. However, the direction of this association is yet to be explored. The available data did not allow us to estimate the number of potentially eligible patients that could be referred to the NLC or the characteristics of patients, which could influence follow-up care preferences. In the future, prospective studies should explore both clinical and personal characteristics of patients who are most likely to benefit from NLC.

Published literature on NLC models often lacks detailed descriptions of the evaluated models, limiting the potential for a broader adoption [13, 15]. Given the importance of the structure of the intervention and contextual factors in the evaluation and implementation of complex interventions as models of care [15], a detailed description of the evaluated model of care represents an important strength of this study. We used the Framework for Reporting Health Service Delivery Models for Managing Rheumatoid Arthritis [35] to discuss details of the NLC and RLC models' implementation, their goals, target population, care providers and their roles, and services provided. Importantly, in contrast with most evaluated NLC models for patients with RA [13], this study evaluated a model which employs registered nurses without an advanced practice designation. Advanced practice nurses (e.g., nurse practitioners, clinical nurse specialists) require additional training and generally are paid a higher salary than registered nurses, which

should also be considered when estimating costs of NLC models. Thus, in the light of financial constraints in healthcare systems, a model utilizing registered nurses with additional rheumatology training to their full scope of practice might be particularly attractive to decision-makers. Our non-inferiority study with 1-year follow-up provides a foundation for future evaluations of the model's long-term effectiveness and cost-effectiveness.

CONCLUSIONS

This study provided real-world evidence that the evaluated NLC model providing protocolized follow-up care for stable patients with RA represents an effective strategy to address the needs of stable patients with RA for ongoing disease monitoring, chronic disease management, education, and support. In the model, registered nurses act in an alternative role to monitor patients' disease activity in lieu of a rheumatologist; and in complementary roles to provide patients comorbidity screening and education, as well as to support standardized clinic documentation and communication with PCPs. In the context of the limited capacity of rheumatologists, NLC is one approach to consider for providing better access to effective and appropriate care for stable patients with RA.

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Compliance with Ethics Guidelines. This study was performed in accordance with the Helsinki Declaration of 1964 and its later amendments. The project was approved by the University of Calgary Health Research Ethics Board (REB17-1678). The approval included a waiver of patient consent for this research and publication due to the limited feasibility of obtaining patients' consents for the collection and analysis of retrospective data and the publication of results as well as the minimal risks or discomforts associated with the research.

Data Availability. The datasets generated during and/or analyzed during the current study may be available from the corresponding author on reasonable request.

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