Impact of rapid infliximab infusions on access at a large academic tertiary medical center

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Purpose. Infliximab promotes remission in patients with inflammatory bowel disease (IBD) and rheumatologic disease (RD). Rapid infliximab infusions (RI) reduce infusion time from 2 hours to 1 hour and can enhance access to care, as defined by capacity, safety, and patient characteristics. Our hypothesis for the study described here was that use of RI can enhance access for patients.

Methods. Data on all patients receiving infliximab for IBD or RD at our outpatient infusion center from February 2016 to August 2017 were retrospectively analyzed. Demographic and clinical information were collected.

Results. Of 348 patients who received infliximab, 205 had IBD and 143 had RD. In terms of capacity, 40% of patients received RI, resulting in a 16.1% decrease in average daily infusion time and a 9.8% increase in average daily available scheduled infusion chair time ($P = 0.720$). In terms of safety, 4 patients switched back to standard infusions after RI, after 3 specifically had reactions to RI. In terms of patient characteristics, more patients with RD versus IBD received RI ($P = 0.020$). Among the patients with RD, a lower proportion receiving RI were female ($P = 0.043$). For the patients with IBD, a higher proportion receiving RI were White ($P = 0.048$). Among both patients with RD and patients with IBD, a higher proportion receiving RI had private insurance ($P = 0.016$ and $P = 0.018$, respectively).

Conclusion. RI were safe and increased available chair time. Females with RD, patients of non-White race with IBD, and patients with public insurance were less likely to receive RI. Future directions include patient surveys and evaluation of implicit bias against patient factors that may impact access to RI.

Keywords: health services accessibility, inflammatory bowel disease rheumatologic disease, infliximab, rapid infusion, time factors

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Infliximab has been used to induce and maintain remission in patients with inflammatory bowel disease (IBD), including ulcerative colitis (UC) and Crohn's disease (CD),[1,2] as well as various rheumatologic disorders (RD) such as rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis.[3-5] However, infliximab infusions are time intensive and, given the need for ongoing infusions, can place a great burden on patients and the healthcare system. Rapid infliximab infusions (RI), which reduce infliximab infusion time from 2 hours to 1 hour, may alleviate this burden and enhance access to care. According to Guillford and colleagues,[6] access to care is defined as service effectiveness, availability, and equitable service utilization; access will be defined here according to safety, capacity, and patient characteristics.

Investigators have demonstrated the safety of RI. A meta-analysis of RI in patients with IBD, rheumatoid arthritis, spondyloarthropathy, and psoriatic disease demonstrated there is no association with increased risk of infliximab infusion reactions with use of RI compared to standard infusion times.[7] This has similarly been demonstrated in patients with IBD only,[8-21]

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with no significant difference in loss of response (meaning progression of disease despite treatment) between 1- and 2-hour infusions.[22]

RI have been shown to enhance infusion suite capacity, leading to an increase of 9% to 50% in total infusions.[8,10,18,20] Cost savings per rapid infliximab infusion have been noted to be $150 to $300.[7,8] Including costs due to productivity loss, Mazzouli et al[14] showed RI led to a relative administration cost reduction of 46.8%.

We aimed to describe the impact of RI on access at our large infusion center in terms of safety, capacity, and patient characteristics, with the hypothesis that RI enhance access to care for all patients regardless of disease indication.

KEY POINTS

- In regard to capacity, 40% of patients received rapid infliximab infusions (RI), with a 16.1% decrease in average daily infusion time and a 9.8% increase in average daily available scheduled infusion chair time.
- In regard to safety, 4 patients receiving RI switched back to standard infliximab infusions, 3 after a reaction to RI.
- In regard to patient characteristics, females with rheumatologic disease, patients of non-White race with inflammatory bowel disease, and patients with public insurance were less likely to receive RI.

Methods

Data on all patients treated with infliximab for either IBD or RD at our single outpatient infusion center from February 1, 2016, to August 31, 2017, were retrospectively analyzed. RI were initiated in our center on February 15, 2017. A rapid infliximab infusion was defined as infusion at a rate of 100 mL/h for 15 minutes followed by infusion at a rate of 300 mL/h over a total of 1 hour, as opposed to the standard infliximab infusion time of 2 hours.

Our infusion center transitioned to an electronic medical record (EMR) in July 2017, at which point pre-EMR data were migrated to our current EMR. Demographic data including age, gender, race, ethnicity, and insurance status were collected. Clinical data including IBD/RD diagnosis and history of previous treatment with biologics were collected. Data on infliximab use, including duration of use; dosing; history of infusion reaction; whether samples for infliximab antibody tests were ever drawn and results of said tests; need for premedications (namely, diphenhydramine, acetaminophen, and/or methylprednisolone, per our policy selected at the discretion of the prescribing physician and given 30 minutes prior to the infusion); number of standard infusions and RI in the study period; and aberrancies from dosing schedule, as well as reasons for aberrancies if described, were collected. If patients ever received a rapid infusion of infliximab, they were categorized in the RI group.

Our standardized protocol for conversion to RI was led by pharmacists and infusion staff nurses. Staff prospectively identified patients for conversion. Patients were eligible to transition from standard infliximab infusions to RI if they met the following criteria: (1) received a minimum of 6 infusions at the standard rate (2 hours, including 3 induction doses and 3 maintenance doses) and (2) staff reviewed risks and benefits with the patient and the patient agreed to a pharmacist contacting the prescriber to convert to RI. Exclusion criteria included (1) a history of infusion reaction not prevented with premedications and (2) receipt of infliximab doses greater than 1,000 mg. At any time, postconversion patients could elect to return to a standard infusion rate.

Categorical variables were summarized with frequencies and percentages, and chi-square tests or Fisher's exact tests were used to assess differences between groups, as appropriate. Means and standard deviations summarized the continuous variables, and *t* tests were used to compare groups, with log transformations performed as necessary. Normality was assessed through the use of histograms and normal quantile plots; log transformations were done prior to *t* tests being conducted when the raw data significantly violated the normality assumption but the data on the log scale satisfied the assumptions of the *t* test.

All analyses were conducted with SAS 9.4 (SAS Institute, Cary, NC), and *P* values less than 0.05 were considered to be significant.

The study protocol and the associated personnel participation were approved by our institutional review board.

Results

Overall population. There were 348 patients getting infliximab infusions during the study period. One hundred ninety-three patients (55%) were receiving infliximab solely for the indication of IBD, and 143 patients (41.1%) were receiving infliximab solely for RD; 12 patients were receiving infusions for both IBD in addition to an RD indication. The average patient age was 46.07 years. Patients receiving infliximab for RD were older than patients with IBD ($P < 0.001$). Approximately 61% of patients were female. Patients receiving infliximab for RD were more likely to be female than those with IBD indications ($P = 0.019$). The majority of patients were White and had private insurance. There was a higher proportion of patients with private insurance among patients with IBD versus patients with RD ($P = 0.026$) (Table 1).

Rapid infusion capacity. During the study period 140 patients (40.23%) received RI: 68 with RD and 72 with IBD. At the initiation of the study period the infusion suite had 9 infusion chairs and was open for 9 hours daily. Total available chair time

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Table 1. Patient Demographics in Overall Population and by Disease Indication

Variable	Overall (n = 348)	Rheumatologic Disease (n = 143)	Inflammatory Bowel Disease (n = 205)[a]	P Value[b]
Female sex, No. (%)	213 (61.21)	98 (68.53)	115 (56.10)	0.019
White race, No. (%)	273 (78.45)	109 (76.22)	164 (80.00)	0.399
Private insurance, No. (%)	228 (65.22)	84 (58.74)	144 (70.24)	0.026
Tried prior biologic therapy, No. (%)	92 (26.44)	43 (30.07)	49 (23.90)	0.199
History of infliximab antibodies, No. (%)[c]	. . .[d]	. . .[d]	3 (4.55)	. . .[d]
History of infusion reaction, No. (%)	21 (6.03)	5 (3.50)	16 (7.80)	0.097
Premedication, No. (%)	117 (33.62)	40 (27.97)	77 (37.56)	0.063
≥1 missed/late infusion, No. (%)	109 (31.32)	48 (33.57)	61 (29.76)	0.451
Rapid infusion, No. (%)	140 (40.23)	68 (47.55)	72 (35.12)	0.02
Age, mean (SD)[e]	46.07 (16.44)	57.16 (13.13)	38.33 (13.91)	<0.001
Years on infliximab, mean (SD)[d]	6.35 (4.69)	7.39 (5.16)	5.63 (4.20)	0.001

[a]Twelve of the 205 patients who received infliximab for inflammatory bowel disease also received it for rheumatologic disease.
[b]P values from chi-square tests or t tests.
[c]Only 66 of 205 patients (32.19%) with inflammatory bowel disease had infliximab antibodies evaluated, and no patients with rheumatologic disease had antibodies evaluated.
[d]Not applicable.
[e]Variable log transformed for analysis.

was 3,240 minutes daily. Available scheduled time was 2,835 minutes daily, taking into account staggered nursing start times as well as time for nurse meal and break times. The infusion suite was filled, on average, at 94.5% of capacity (for a mean [SD] total of 2,679.12 [118] minutes per day). Standard infliximab infusions were scheduled for a total of 150 minutes per infusion, which allowed 15 minutes for laboratory test sampling, intravenous line placement, and medication preparation, as well as 15 minutes post infusion for chair turnover. Patients receiving RI were scheduled for a total of 90 minutes. At baseline, infliximab accounted for 62% of total occupied chair time (a mean [SD] of 1,661 [142] minutes per day) at the infusion center. With 40% of patients transitioned from standard infusions to RI during the study period, there was an average daily infliximab infusion time of 1,394.6 minutes (SD, 98 minutes), representing a 16.1% decrease. The calculated impact of the conversion was a 9.8% increase in average daily scheduled available chair time, or an additional 261.2 (SD, 19.7) minutes per day (P = 0.720).

Rapid infusion safety. Only 4 patients (2.9%) had documentation in their chart indicating that they had to switch back to standard infusions from RI, with 3 of those patients specifically switched after RI reactions during the study period. One patient had received 3 RI for RD in the study period but had a mild itching reaction and was switched from RI to standard infusions. Three patients receiving RI for IBD were switched back to standard infusions after their first and only rapid infusion in the study period; one patient had a mild reaction ("falling ill") and one had a reaction listed as "had reaction to the rapid infusion." One patient treated during the study period was noted to have "one rapid [infusion] and [was] then switched back to 2 hours, reasons unclear"; the same patient had had an infusion reaction (erythema) at the injection site 3 years previously.

A minority of patients (33.6%) received premedications prior to infusions (Table 1). Patients receiving standard infusions were more likely to receive premedication (P < 0.001, Table 2). A significantly larger proportion of patients with RD receiving only standard infusions versus RI received premedication (41.33% vs 13.24%, P < 0.001; Table 3). There was no significant difference in rates of premedication administration before standard infusions versus RI for patients with IBD (41.35% vs 30.56%, P = 0.128; Table 4).

Overall 31.32% of patients had at least 1 off-cycle infusion, defined as receiving an infusion that was either missed or received later than the prescribed scheduled time interval, with no significant difference between patients with IBD and those with RD (Table 1). The majority of patients did not have a documented reason for an off-cycle infusion; for those who did, documented reason types included infection related (n = 13, including 2 patients with a positive tuberculosis screening test), surgery related (n = 4), participation in a clinical trial for a neurologic disease (n = 1), and vacation (n = 1). Additionally, 6 females had infusions intentionally held secondary

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Table 2. Patient Demographics and Safety Factors by Infusion Type

Variable	Standard Infusion Only (*n* = 208)	At Least 1 Rapid Infusion (*n* = 140)	*P* Value[a]
Female sex, No. (%)	137 (65.87)	76 (54.29)	0.030
White race, No. (%)	156 (75.00)	117 (83.57)	0.057
Private insurance, No. (%)	123 (59.13)	105 (75.00)	0.002
Tried prior biologic therapy, No. (%)	55 (26.44)	37 (26.43)	0.998
History of infliximab antibodies, No. (%)	2 (5.13)	1 (3.70)	1.000[b]
Premedication, No. (%)[c]	86 (41.35)	31 (22.14)	<0.001
Age, mean (SD), y[d]	44.96 (16.75)	47.71 (15.88)	0.081
Years on infliximab, mean (SD)[d]	5.22 (4.25)	8.04 (4.82)	<0.001
No. of standard infusions, mean (SD)	8.19 (4.04)	8.40 (2.75)	. . .[e]
No. of rapid infusions, mean (SD)	. . .[e]	2.44 (1.53)	. . .[e]

Abbreviation: SD, standard deviation.
[a]*P* values from chi-square tests unless otherwise noted.
[b]*P* value from Fisher's exact test.
[c]Premedications included diphenhydramine, acetaminophen, and/or methylprednisolone.
[d]Variable log transformed for analysis.
[e]Not applicable.

to being peripartum. One patient had infliximab held 1 year due to precancerous appendix lesions. Another unique reason for off-cycle infusions was insurance-related approval delays; this reason was specifically noted for 6 patients, with 1 of these patients having to be reinduced with infliximab because of the 9-month insurance-related delay. These 6 patients were all receiving standard infusions, and all had private insurance.

Infliximab antibody testing was performed only for IBD-treated patients, and only 3 of 66 patients tested were found to have detectable antibodies. One of the 3 patients with detectable antibodies had RI but switched back to standard infusions after having a reaction recorded as "feeling ill." Of note, the rapid infusion reaction occurred about 4 months before the positive test for infliximab antibodies; upon a recheck for antibodies about 1 year later, no antibodies were detected. The other 2 patients had standard infusions; 1 had a history of a mild infusion reaction (Table 4).

Rapid infusion patient characteristics. A larger proportion of patients with RD versus IBD received RI: 68 of 143 (47.6%) and 72 of 205 (35.1%), respectively ($P = 0.020$; Table 1). Within the RD subset only, a lower proportion of patients receiving RI were female ($P = 0.043$, Table 3); in the IBD subset only, a higher proportion of patients receiving RI were of White race ($P = 0.048$; Table 4). Among both patients with RD and patients with IBD, a higher proportion receiving RI had private insurance ($P = 0.016$ and $P = 0.018$, respectively). For both indications, patients receiving RI had been on infliximab for a longer period of time (Table 3 and Table 4).

Discussion

Access to care can be defined by capacity, safety, and patient characteristics. Our study demonstrated that RI increased availability at a large infusion center, specifically chair capacity. Consistent with findings in prior studies, RI were safe. Our study was unique in that we included patients receiving infliximab for both IBD and RD and found significant differences in the characteristics of patients receiving RI, including gender, race, insurance status, and time on infliximab, suggesting perhaps nonequitable service utilization.

In terms of general infusion safety, ascertainment of specifics regarding the history of infusion reactions noted for patients on standard infusions and on RI was limited by the retrospective nature of the study, as a history of infusion reaction was often noted without documentation of details on the timing or exact type of the reaction. With regard to patients who received RI in the study period, while 4 patients had a chart notation indicating that they were switched from RI to standard infusions, for 3 of them there was chart documentation indicating the switch was made after a reaction to a rapid infusion. The 2 reactions that were specified were mild. In pertinent research publications identified in our review of the literature, one group of investigators reported no infusion reactions in a study in which 54 patients received RI,[20] while another study demonstrated that 2.9% of patients receiving RI had loss of tolerability due to infusion reactions[22]; in the third study identified, 9 of 102 patients (8.8%) receiving 1-hour infliximab infusions experience mild reactions not requiring discontinuation of infliximab.[21] Thus, the frequency of a need to switch from RI back to standard infusions in our study was comparable to that reported in other studies.

We described that 33.62% of patients in our study received premedications before their infusion. Other groups have described rates of premedication use ranging from 12.2% to 100%,[12,14,22] although others have demonstrated that premedication is not associated with preventing infusion reactions.[8,10,11,15,19] Our data on infliximab antibodies was not robust because testing was performed only among IBD patients. Interestingly, 1 of the 3 patients with IBD with detectable antibodies had RI but switched back to standard infusions after having a reaction to rapid infusion of infliximab, and upon a recheck of antibodies about 1 year later no antibodies were detected. None of the literature reviewed

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Table 3. Patient Demographics and Safety Factors by Infusion Type for Rheumatologic Disease Indication

Variable	Standard Infusion Only (*n* = 75)	At Least 1 Rapid Infusion (*n* = 68)	*P* Value
Female sex, No. (%)	57 (76.00)	41 (60.29)	0.043[a]
White race, No. (%)	55 (73.33)	54 (79.41)	0.394[a]
Private insurance, No. (%)	37 (49.33)	47 (69.12)	0.016[a]
Tried prior biologic therapy, No. (%)	22 (29.33)	21 (30.88)	0.840[a]
Premedication, No. (%)	31 (41.33)	9 (13.24)	<0.001[b]
Age, mean (SD), y	57.00 (13.56)	57.33 (12.73)	0.881[b]
Years on infliximab, mean (SD)[c]	5.96 (4.70)	8.96 (5.23)	<0.001[b]
No. of standard infusions, mean (SD)	9.59 (4.27)	9.07 (2.6)	. . .[d]
No. of rapid infusions, mean (SD)	. . .[d]	2.43 (1.25)	. . .[d]

Abbreviation: SD, standard deviation.
[a]*P* values from chi-square tests.
[b]*P* values from *t* tests.
[c]Variable log transformed for analysis.
[d]Not applicable.

Table 4. Patient Demographics and Safety Factors by Infusion Type for IBD Indication

Variable	Standard Infusion Only (*n* = 133)	At Least 1 Rapid Infusion (*n* = 72)	*P* Value[a]
Female sex, No. (%)	80 (60.15)	35 (48.61)	0.112[a]
White race, No. (%)	101 (75.94)	63 (87.5)	0.048[a]
Private insurance, No. (%)	86 (64.66)	58 (80.56)	0.018[a]
Tried prior biologic therapy, No. (%)	33 (24.81)	16 (22.22)	0.678[a]
History of infliximab antibodies, No. (%)	2 (1.50)	1 (1.39)	1.000[b]
Premedication, No. (%)	55 (41.35)	22 (30.56)	0.128[a]
IBD, No. (%)	. . .[c]	. . .[c]	0.548[a]
Crohn's disease, No. (%)	104 (79.39)	53 (75.71)	. . .[c]
Ulcerative colitis, No. (%)	27 (20.61)	17 (24.29)	. . .[c]
Age, mean (SD), y	38.17 (14.43)	38.63 (12.98)	0.613[d]
Years on infliximab, mean (SD)[e]	4.80 (3.94)	7.16 (4.26)	<0.001[d]
No. of standard infusions, mean (SD)	7.40 (3.69)	7.76 (2.74)	. . .[e]
No. of rapid infusions, mean (SD)	. . .[c]	2.46 (1.76)	. . .[c]

Abbreviations: IBD, irritable bowel syndrome; SD, standard deviation.
[a]*P* values from chi-squared tests.
[b]*P* value from Fisher's exact test.
[c]Not applicable.
[d]*P* value from *t* test.
[e]Variable log transformed for analysis.

discussed antibody formation in relation to RI; thus, future research directions could include elucidating the risk of immunogenicity in both the IBD and RD populations and its impact on tolerability of RI.

We found that almost one-third of patients had at least 1 off-cycle infusion. This finding is important as it could potentially have safety implications for patients, including increased risks of infusion reactions and development of antibodies.[8] There were 6 patients for whom it was specifically noted in the chart that insurance delays in covering an infusion were the only reason for off-cycle infusion. Subsequent infusions were standard only. This finding emphasizes the importance of enhancing access to infusions along with appropriate timing of scheduled doses to reduce adverse events.

Patients receiving RI versus standard infusions for both IBD and RD had been receiving infliximab for a significantly longer time, which might have been due to organizational policy that patients must have tolerated 6 standard infusions before proceeding to RI; it could also represent patient and provider comfort based on treatment duration history. Overall, while the safety of RI has been demonstrated, organizational rules and perceptions of patients and providers regarding the safety of RI could be barriers to implementation of RI.

In regard to infusion capacity, because our infusion center began administering RI in February 2017 and our study window closed in August 2017, 40.2% of patients were converted to RI. While the total gain in available scheduled time was not significant, the scheduled capacity remained above 94%. This allowed for additional access as well as an overall net increase in infusion revenue and a decrease in paid nursing overtime. The increase in unit capacity was noted by other groups of researchers who also explored patient and nurse satisfaction with RI.[10,13,14,20,23] Future efforts could be aimed at prospectively enrolling patients and healthcare personnel to

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track their satisfaction over time as they switch from standard infusions to RI. Additionally, further understanding the costs, including direct and indirect productivity gains, with RI would be helpful for the purpose of making an optimal infusion experience for patients and healthcare systems.

The most unique aspects of our study were that we included patients receiving infliximab for RD as well as for IBD and that we found differences in service utilization based on patient characteristics. We found a larger number of patients with RD versus IBD received RI. It is unclear if this result is related to provider experience and comfort with RI (ie, among rheumatologists vs gastroenterologists) or if there are patient-related factors influencing this decision. Among RD patients only, we found significantly less females were getting RI. And among IBD patients only, significantly more White patients were getting RI. Strikingly, for both patients with RD and those with IBD, significantly more patients with private insurance received RI. To our knowledge, there are no published studies that demonstrate a physiologic difference in tolerance of RI based on gender or race. We are not aware of public insurance mandates requiring a separate infliximab prior authorization to get RI. As demonstrated by prior economic studies,[14] RI are more cost-effective, which would lead us to believe both public and private insurers would support RI.

As with any retrospective study, there were limitations of our study. First, discrete details such as patient selection for RI, reason for prescriber or patient preference for infusion duration, use of or indication for premedication, details on infusion reactions reported, infliximab antibody testing, and reasons for off-cycle or delayed infusions could not be ascertained unless they were explicitly reported. The estimate of how RI increased access to care due to available chair utilization may also be skewed, as 3 additional infusion chairs were purchased for the infusion center during the study period. However, the chair fill time of greater than 94% demonstrated that even with the additional chairs, capacity had improved.

Conclusion

Our initial study hypothesis that RI enhance access to care (defined by capacity, safety, and patient characteristics) for all patients, regardless of indication for infliximab, was not fully supported by our data. While we demonstrated safety and capacity enhancement with use of RI, there were differences in patient characteristics. Namely, females with RD, non-White patients with IBD, and all patients with public insurance appeared to have not been receiving RI at the same frequency as their White and/or male counterparts with private insurance. Furthermore, 6 patients had delays in getting the treatment they needed that were specifically due to insurance delays in coverage, and once the patients were finally approved to get their infliximab infusions, they received only standard infusions; it is unclear why that was the case. Thus, future study directions may include the creation of a prospective registry to understand if implicit or structural bias related to disease, gender, race, socioeconomic status, patient or provider preferences, or other factors such as medical or psychosocial comorbidities impact overall access to RI. Future work will also educate providers on this data, review the RI protocol so that they can equitably offer RI to their patients, and help providers identity implicit bias that may impact their prescription practices.

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Disclosures

Dr. Afzali has received consulting fees from and/or served on the speakers bureaus of Abbvie, Janssen, Takeda, Pfizer, Bristol Myers Squibb/Celgene; and has served on an advisory board for Abbvie, Janssen, Takeda, and Bristol Myers Squibb/Celgene. The other authors have declared no potential conflicts of interest.

Additional information

All persons listed as authors made substantial contributions to the conception or design of the work or the acquisition, analysis, or interpretation of data for the work; drafted the work or revised it critically for important intellectual content; provided final approval of the current version; and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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