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Retrospective, Multicenter Study of Clinical and Economic Outcomes Associated with Accelerated Infliximab Home Infusion

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Background

Biologic agents and other specialty medications, including infliximab (Remicade®), are effective therapies used in various disease states but are also costly, accounting for more than twenty percent of drug spending in the United States.[1,2] Infliximab is a monoclonal antibody anti-tumor necrosis factor used in the treatment of Crohn's disease, ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis, plaque psoriasis, and psoriatic arthritis.[2,3,4] It is typically administered intravenously at a dose of 5 mg/kg as a standard 2-hour infusion.[2,4] Beginning in 2004, researchers have discovered that it can be administered safely as a 1-hour infusion.[3,5] While accelerated infusions can increase cost savings, patient satisfaction, and quality of life, safety is also critical to successful outcomes. [1,2,3]

Acute infusion reactions, including erythema, chest tightness, and paresthesia occurred during or within 1 hour after infliximab infusion.[1] Delayed infusion reactions such as myalgia, arthralgias, and fevers, occurred between 1 and 14 days after infliximab infusion. Severe infusion reactions include decreased consciousness and hypotension.[1,6]

Purpose

This study evaluated the impacts of decreasing infliximab infusion time from the standard two-hour infusion to a rapid one-hour infusion, in order to 1) monitor incidence and severity of adverse events, 2) assess improvement in adherence, and 3) reduce costs, both tangible and intangible.

Methods

This study was a retrospective, non-randomized, multi-centered, observational study. Two hundred and twenty patients from forty-eight care management centers who transitioned from standard Remicade® infusion to accelerated infusion between January 2020 and December 2020 were assessed. Patient records were de-identified prior to analysis. Patients were eligible for the accelerated infusion if they previously tolerated at least four 2-hour infusions without any report of adverse events.[5] Prior to starting rapid infusion, they were required to complete an informed consent form. Primary outcomes included reported adverse events or adverse drug reactions (reported as percentage). Secondary outcomes included adherence, hospitalizations (reported as frequency), and cost outcomes (reported in dollars).

The standard two-hour infusion protocol consisted of a flat rate of 125 mL/hr for 2 hours, followed by monitoring the patient for one hour for the first infusion and thirty minutes for subsequent infusions. Contrastingly, the recommended rate for the rapid infusion protocol is 100 mL/hr for 15 minutes followed by 300 mL/hr for 45 minutes. Patients were monitored for 30 minutes after infusion. During and post-infusion, a specialized home infusion nurse would register infusion data (rate, duration, patient's response) and vital signs (blood pressure and heart rate). Treatment would be either stopped or slowed if an acute reaction occurred.

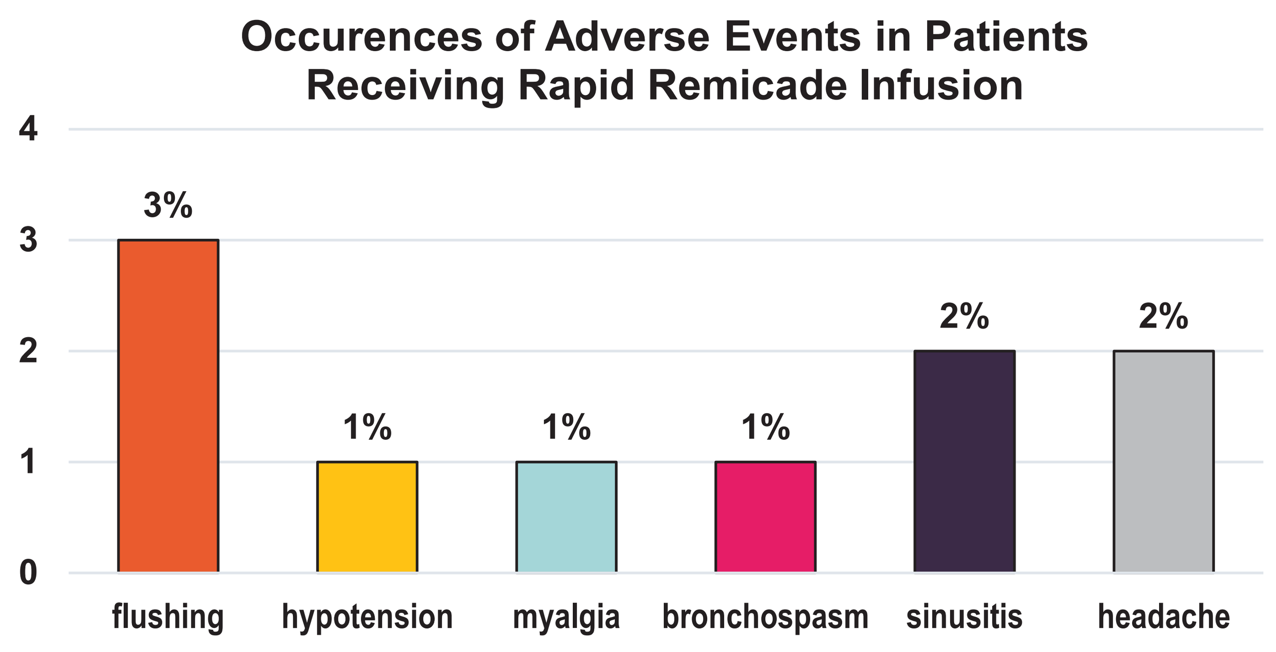
Results

A total of two hundred and twenty patients from forty-eight care management centers were included and studied. In total, 616 hours were saved through utilizing the rapid infliximab infusion protocol. Of two hundred and twenty patients, seven patients (3%) experienced an increase in adverse events with accelerated infusion. Of note, the most commonly reported adverse event was flushing (1.3%). Two patients experienced severe reactions, one of which experienced bronchospasm (0.5%) and the other hypotension (0.5%). The remaining patients experienced flushing (1.3%), myalgia (0.5%), sinusitis (0.9%), and headache (0.9%).

Summary table of patients that switched from standard Remicade® infusions to rapid Remicade® infusions (N=220 patients)

Gender	
Male	114 (51.8%)
Female	106 (48.2%)
Age (range)	
<18	18 (11-17)
18-49	140 (18-49)
50-64	56 (50-64)
65+	6 (66-80)
Frequency of infusions	
Every 4 weeks	35 (16%)
Every 6 weeks	52 (24%)
Every 7 weeks	14 (6%)
Every 8 weeks	116 (53%)
Every 10 weeks	2 (1%)
Every 12 weeks	1 (0.5%)
Disease	
Crohn's	135 (61%)
Ulcerative colitis	57 (26%)
Ankylosing spondylitis	8 (4%)
Rheumatoid arthritis	8 (4%)
Psoriasis	6 (3%)
Immunodeficiency	2 (1%)
Sarcoidosis	1 (0.5%)
Chronic iridocyclitis	1 (0.5%)
Hidradenitis suppur	1 (0.5%)

Figure 1: *Please note that some patients experienced more than one side effect*



Discussion

To date, the conversion to rapid infusion is occurring at fifty-seven care management centers. The accelerated infusion regimen was found to be safe and well tolerated with an observed reaction in only 3% of patients included in the study. The incidence of infusion related reactions with the rapid infusion rate was low at 3% compared to a reported 3.9% in previous studies.[7] Patients who experienced reactions during the rapid infusion were between the ages of 31 and 80 years old. All of the patients who experienced reactions were diagnosed with either Crohn's disease or ulcerative colitis. None of these patients required the use of an anaphylaxis kit nor were they hospitalized following their reactions. Instead, interventions included continuing at the rapid infusion rate as requested by patient (1 of 7 patients), slowing the infusion rate back to the standard two hour infusion (5 of 7 patients), and stopping the infusion (1 of 7 patients). For those that experienced rapid infusion-related reactions, no correlation was found between age, dose, and frequency.

Potential limitations of the study include non-reporting of adverse events by patients, keeping in mind that some reactions were acute and some delayed. The study sample size may also be limited. The process of converting patients from the standard two-hour infusion to the rapid infusion has been gradual.

The average costs associated with nursing time per hour is $70,[8] which is likely to be an underestimation. When considering the time saved for nursing, 616 nursing hours were saved, totaling $43,120. The average cost savings per patient totals $550.77 annually.

Conclusion

Decreasing two-hour to one-hour infusion has shown to be safely tolerated and has resulted in saving nursing and patient time in addition to reducing the cost of nursing visits. Future studies may be established to evaluate the differences between infusion-related reactions in patients solely receiving two-hour infusions compared to those who have been switched to the one-hour infusions. In light of the pandemic, rapid Remicade® infusion lead to decreased exposure time for both nurses and patients and also improved the cost effectiveness of these infusions.

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Disclosures

Authors of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation: Monique Miller, Maria Giannakos, Joseph Soultatos, Christopher Roy, Craig Gardner: Nothing to disclose.

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