Adverse Events and Compliance among Inflammatory Bowel Disease Patients Treated with Home versus Office Based Biologic Infusions

Christopher Schmoyer MD MS[1], Kelly Sun BS[2], Jeremy Zack BS[2], Priyanka Kumar MD[2], Raina Shivashankar MD[2]

[1]University of Pennsylvania, Division of Gastroenterology and Hepatology

[2]Thomas Jefferson University Hospital, Division of Gastroenterology and Hepatology

Background

Home based infusion of Infliximab and Vedolizumab for Inflammatory Bowel Disease (IBD) has expanded due to insurance requirements and patient preference.

- Previous data suggest increased rates of adverse events and reduced efficacy of biologics when given at home rather than in a medical office.
- It remains unclear if this trend is true for all institutions.
- It is also unclear whether patient adherence to periodic clinic follow-up, routine laboratory monitoring, or accurate weight based dosing of Infliximab is reduced in those who are infused at home.

Methods

- Single center retrospective cohort study
- Included all adult patients with IBD receiving Infliximab or Vedolizumab either at home or at an office based infusion center.
- Primary AIM – Compare the safety of home and office based biologic infusions
  - AEs were defined as immediate (<24 hour) and delayed (day 1-7) transfusion reaction, steroid initiation, drug discontinuation, or IBD-related emergency room visits, admission, and surgery.
- Secondary Aims
  - Identify differences in patient compliance between home and office infusions. Defined as adherence to clinic visits and lab studies for drug monitoring at 6 month intervals
  - Ensure quality of Infliximab infusions by comparing the frequency of pre-transfusion weight checks and correct weight based dosing
- Chi squared and Fisher's exact tests were used, where appropriate, to determine statistical significance. Kaplan-Meier plot created using SPSS software.

Results

Table 1: Demographics and IBD Characteristics. Home infusion patients tend to be younger, female, with less former smokers. They also had shorter disease duration, less severe disease based on Harvey Bradshaw Index, and less likely to be on mesalamine.

		Home Infusion n = 154	Office Infusion n = 133	
Age		37.3 (12.2)	45.0 (16.4)	p <0.05
Female		81 (52.6%)	52 (39.1%)	p <0.05
Race				
	Non-Hispanic White	131 (85.1%)	102 (77.3%)	
	Black	12 (7.8%)	21 (15.9%)	
	Asian	6 (3.9%)	5 (3.8%)	
	Hispanic	4 (2.6%)	2 (1.5%)	
	Other	1 (0.6%)	2 (1.5%)	
BMI		27.7 (6.5)	27.0 (6.5)	
Current Smoker		10 (6.5%)	10 (7.6%)	
Former Smoker		29 (19.0%)	47 (35.9%)	p <0.05
Disease Duration (Years)		8.1 (8.1)	11.2 (12.6)	P <0.05
Previous IBD Surgery		39 (26.2%)	37 (28.9%)	
Harvey Bradshaw Index		3.9 (2.9)	4.8 (3.8)	p <0.05
Ulcerative Colitis		61	50	
	Proctitis	12 (19.7%)	13 (26%)	
	Left-Sided	16 (26.2%)	13 (26%)	
	Pancolitis	33 (54.1%)	24 (48%)	
Crohn's Disease		93	83	
	Ileal	25 (26.9%)	24 (28.9%)	
	Colonic	22 (23.7%)	19 (22.9%)	
	Ileocolonic	42 (45.2%)	40 (48.2%)	
	Upper GI	4 (4.3%)	1 (1.2%)	
	Inflammatory	52 (55.9%)	42 (50.1%)	
	Stricturing	18 (19.4%)	26 (31.3%)	
	Fistulizing	23 (24.7%)	15 (18.1%)	
	Perianal	26 (27.1%)	21 (22.8%)	
Concurrent Medication				
	Mesalamine	30 (19.6%)	44 (33.3%)	P <0.05
	Thiopurines	14 (9.2%)	15 (11.4%)	
	Methotrexate	3 (2.0%)	9 (6.8%)	
Biologic Use				
	Naive	86 (56.2%)	74 (55.6%)	
	Previous Use	67 (43.8%)	59 (44.4%)	
	# Previous Biologics	1.4 (0.7)	1.5 (0.7)	

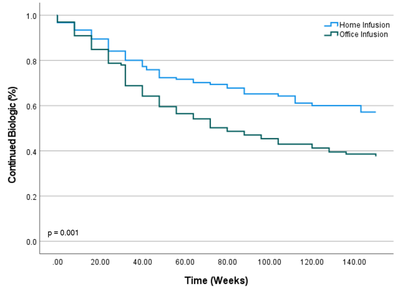

Figure 1: Major Adverse Event Free Survival Between Home and Office Biologic Infusion. During 152 weeks of observation, adverse events were seen in 60.7% of office based infusions compared to 36.4% of those receiving home infusions. The difference was significant on Log Rank analysis (p=0.001).

		Home Infusion	Office Infusion	
Major Adverse Event		55	80	p < 0.5
	Transfusion Reaction, Immediate	7	9	
	Transfusion Reaction, Delayed	0	4	p < 0.5
	ED Visit	0	1	
	Admission	7	6	
	Surgery	0	6	p < 0.5
	Steroid Initiation	6	10	
	Discontinuation	35	44	p < 0.5

Table 2: Frequency of Individual Major Adverse Events Among Home and Office Biologic Infusions. Major adverse events are significantly increased among those receiving home infusions (80 vs 55). This driven by higher rates of drug discontinuation, delayed transfusion reaction, and IBD related surgery.

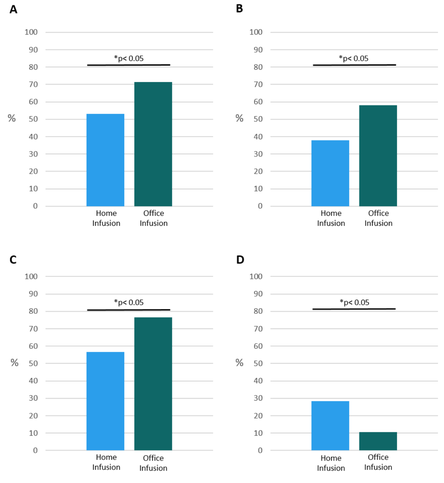

Figure 2: Patient Compliance and Accurate Weight Based Dosing is Decreased with Home Infusion. A) Presence at biannual office visits. Home 53.2% vs Office 71.4%. B) Compliance with biannual drug monitoring. Home 37.9% vs Office 58.1%. C) Weight obtained prior to Infliximab Infusion. Home 56.7% vs Office 76.6%. D) Incorrect weight based Infliximab dosing. Home 28.3% vs Office 10.7%.

Results Summary

- Incidence of major adverse events were significantly higher for those receiving biologic infusion in an office based seeing compared to home infusion.
- Higher adverse events for office based infusions were driven by drug discontinuation, delayed transfusion reactions, and IBD related surgery.
- Patient compliance was much lower for those with home based infusions with lower frequency of biannual office visits and acquisition of routine labs for drug monitoring.
- Home Infliximab infusion patients were less likely to be weighed prior to administration. When weight was obtained, the incorrect dose was given at much higher rates.

Discussion

- In this study, higher adverse events were seen in those receiving biologics through office based infusion. This runs contrary to some published data which favor the safety of office based administration.
- Treatment bias may exist towards starting home infusions in more stable patients given less severe disease (HBI 3.8 vs 4.9) in that group.
- Limitations inherent to single center studies may also be in play
- In conclusion, home infusion appears to be a viable option for biologic administration assuming patient adherence to followup and correct weight based Infliximab dosing is maintained.