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(REVIEW ARTICLE)

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Evaluating the comparative risk of postoperative complications associated with infliximab and vedolizumab for patients with Crohn's disease

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Abstract

Crohn's disease is an inflammatory bowel disease that affects millions worldwide. Research indicates that people suffering from Crohn's disease respond well to monoclonal antibody treatment aimed at characteristic immune cell markers. By targeting immune cell markers, the immune system is subsequently suppressed in a way such that an infection can evolve much quicker. Monoclonal antibody treatment has historically shown to result in increased rates of post-surgical infections in those taking it for Crohn's disease.

Many studies have assessed the increased rates of post-surgical infections following monoclonal antibody treatment for those with Crohn's disease, but few have compared different treatments.

A systematic review of a study that assessed the rates of postoperative infections for those with Crohn's disease taking infliximab was then compared to the findings of another study which assessed the rates of postoperative infections in those with Crohn's taking vedolizumab.

The patients treated with vedolizumab did not have increased risk of overall postoperative infections or other complications compared with other matched controls. However, those who were treated with infliximab had an increased risk of surgical infections when compared to a control group.

Monoclonal antibody treatment for Crohn's diseases is widespread. It is critical that the side effects of these treatments are readily studied and compared to improve patient outcomes. For this review, infliximab seemed to have a statistically significant increased effect on postoperative infections whereas vedolizumab did not. Further studies with greater sample sizes assessing multiple other side effects of monoclonal antibody immunosuppression are needed.

Keywords: Crohn's Disease; Infliximab; Vedolizumab; Inflammatory Bowel Disease; Monoclonal Antibody Therapy; Postoperative Complications

1. Introduction

There is sufficient information suggesting that persons suffering from Crohn's disease respond well to monoclonal antibody therapy (1). The two prominent subclasses of monoclonal antibody treatments are currently utilized for the treatment of Crohn's are the anti-tumor necrosis factor (TNF) agents such as infliximab and the anti-leukocyte adhesion molecule inhibitors such as vedolizumab (1).

Anti-TNF agents are associated with immunosuppression due to their target of a key factor in the pathogenesis of inflammation which inevitably decreases the host defense (4). Anti-leukocyte adhesion molecule inhibitors prevent the

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adhesion of leukocytes to vascular endothelium such that migration of the leukocytes to infected tissue does not occur (5). It is well known that both monoclonal antibody therapies result in immunosuppression, but little has been done to compare the magnitude of immunosuppression (1). This is particularly important in the case of assessing the comparative likelihoods of postoperative infections of individuals with Crohn's taking either medication.

2. Methods

For the case-matched study on Vedolizumab (3):

Adult patients with Crohn's disease who were treated with Vedolizumab had their last injection within 12 weeks before the procedure that they were undergoing (3). They were matched 1:1 with a control group according to type of surgical procedure, age, and sex (3). The measured outcome was overall risk of early postoperative infectious complications occurring within the first 30 days of the surgery, readmissions, reoperations, surgical site infections, and other infections (3). The VDZ and control groups were subsequently compared using the Pearson $\chi 2$ test and Wilcoxon rank sum (3).

For the case study for those with Crohn's disease treated with Infliximab (2):

Sixty patients received IFX within 3 months of surgery. These patients were compared with 329 patients undergoing ileocolonic resection during the same time period who never received IFX. In an effort to reduce selection bias, the authors also compared the IFX-exposed patients with 69 patients undergoing ileocolonic resection between 1991 and 1997, before IFX availability. Patients who received IFX >3 months before surgery or for the first time after surgery were excluded from the study. Additional exclusion criteria included the use of other TNF-I, initial ileocolonic resection at another institution, diagnosis of UC or indeterminate colitis, other underlying immunodeficiency, and preexisting stoma. Adverse outcomes were assessed for the 30-day postoperative period and included infectious complications (sepsis, intra-abdominal abscess), operative complications (anastomotic leak, reoperation, wound dehiscence), and other complications (urinary complications, readmission rate, 30-day mortality rate). Univariate and multivariate analyses were performed, including usage of other medications (2).

3. Results

For the case-matched study on Vedolizumab (VDZ)(3)

Table 1 Postoperative Complications Between the Groups

Variable	**VDZ n (%)**	**Non-VDZ Control n (%)**	**p value**
Overall infectious complications	5 (14)	3 (8)	0.45
Surgical infectious complications	4 (11)	1 (3)	0.16
Nonsurgical infectious complications	2 (6)	2 (6)	1
Urinary tract infection	2 (6)	1 (3)	0.56
Pneumonia	0	0	-
Positive blood cultures	0	1 (3)	0.31
Superficial SSI	2 (6)	0	0.15
30-day return to operating room	2 (6)	1 (3)	0.56
30-day unplanned hospital readmission	4 (11)	2 (6)	0.37
Mortality	0	0	-

Table 1 A comparison of postoperative complications between the VDZ-treated and control groups is summarized.

Following from the above (Table 1), VDZ-treated patients had similar frequency of complications compared with controls in overall infectious complications (14% versus 8%, p = 0.45), surgical infectious complications (11% versus 3%, p = 0.16), and nonsurgical infectious complications (6% versus 6%, p = 1.00). Additionally, no differences were found in terms of superficial SSI (6% versus 0%, p = 0.15), reoperations (6% versus 3%, p = 0.56), or readmissions (11% versus 6%, p = 0.37). As seen, despite higher absolute numbers and percentages in the VDZ-treated patients, no statistical differences were found. No cases of postoperative pneumonia and no postoperative deaths occurred (3).

For the case study on Infliximab (2):

Table 2 Outcomes of Infliximab (IFX) vs Non-Infliximab (Non IFX) Groups

	Complication	**Non IFX Group**	**IFX Group**	**Pre-IFX Group**	**p-Value**
30-Day Complications	Urinary Complications	0	1.7	0	0.15
	Wound dehiscence	0.3	0	1.4	1
	30-Day Mortality	0	1.7	0	1
30-Day Complications	Readmission Rate	9.4	20	2.9	0.019
	Sepsis	9.7	20	5.8	0.021
	Intraabdominal abscess	4.3	10	4.3	0.1
	Anastomotic Leak	4.3	10	1.4	0.049
	Reoperation	3	8.3	0	0.02

The above (**Table 2)** summarizes the postoperative complications for both the IFX and Non IFX Groups. There was noted to be a statistically significant difference between the Non IFX group and IFX group in terms of readmission rate (p=0.0019), sepsis (p=0.024), anastomotic leaks (p = 0.049), and reoperation (p=0.02). There was not a statistically significant difference in terms of urinary complications (p=0.15), wound dehiscence (p=1.0), 30-day mortality (p=1.0), and intra-abdominal abscesses (p=0.10).

4. Conclusion

Our analysis suggests that while there were no statistically significant increases in postoperative complications in those with Crohn's disease taking vedolizumab, there were statistically significant increases in those taking infliximab. The postoperative complications that increased were quite specific and few but were nonetheless statistically significant in those taking infliximab. This suggests that the immunosuppressive risk of postoperative complications in those with Crohn's disease is greater in those taking infliximab than those taking vedolizumab. The analyses are limited in the sense that they both couldn't accurately control for the dosage of monoclonal antibody treatment, the severity of the Crohn's disease, and possible comorbidities. More research is needed to address the ratio of cost to benefits with one treatment over another so a physician can ensure the right medication is prescribed. Further studies must be conducted in order to address if only certain significantly increased complications in those with infliximab is a result of the therapies metabolic distribution to certain tissues or due to some other tissue-specific etiology.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

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