EFFECTIVENESS AND SAFETY OF RECOMBINANT HERPES ZOSTER VACCINATION IN IBD PATIENTS: A MULTICENTER PROSPECTIVE STUDY

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BACKGROUND/AIM

Patients with inflammatory bowel disease (IBD) have a higher risk of varicella zoster virus infection (VZI) than the general population,largely due to immunosuppressive or biologic therapies[1].Preventing viral reactivation is a relevant clinical goal[2].The recombinant zoster vaccine(RZV, Shingrix)has shown high efficacy and good tolerability in the general population,but data in IBD are limited[1,2].Real-world evidence on its effectiveness and safety profile in this setting is needed to support vaccination strategies and guide clinical practice[2,3].The objective of the study was to assess the effectiveness and safety of the RZV in IBD.

METHODS

From March 2023 to September2024,consecutive IBD patients who received the RZV Shingrix immediately before starting or with ongoing biologics were prospectively enrolled across 9 tertiary IBD centers.Clinical data were collected at baseline.Effectiveness was assessed clinically and defined as the absence of VZI orHZ reactivation during the observation period.Safety outcomes included the occurrence of vaccine-related adverse events(AEs)—such as fever, injection site pain, arthralgia, and others—systematically recorded during the follow-up after each vaccine dose.

RESULTS

A total of 420 IBD patients were included,comprising 215(51.2%)with UC and 205(48.8%) with CD, with a median age of 44 years(**Table 1**).Most patients(95.8%)completed the VZV vaccination cycle.Biologic therapy was ongoing in 319(75.9%)patients,more frequently in CDthan UC($p< 0.001$).During a mean follow-up of 11.0 ± 1.2 months,VZV reactivation occurred in only 0.7% of patients, confirming a high clinical effectiveness of RZV in IBD.Overall,AEs were reported in 52.4% of cases,with the most common being arm pain(37.1%),followed by asthenia(16.0%)and fever(13.8%).No significant differences between UC andCD(54.4% vs 50.2%,$p=0.448$),as for gender($p=0.96$),were found.AE occurrence was significantly associated with ongoing biologic therapy(56.9% vs 29.3% without,$p=0.009$)and lower age (median42 vs 45.5years,$p=0.047$).However,analyzing therapies by specific mechanism of action, including JAKi, no class of drug was associated with a higher AE risk compared to others.Logistic regression confirmed only biologics as an independent risk factor(OR1.84;95%;$p=0.009$).In the subgroup analysis comparing biologics to conventional or no therapy,only asthenia and joint pain were significantly more common in patients on biologics($p<0.001$ and $p=0.04$, respectively).No serious AEs were reported.

CONCLUSIONS

In this prospective cohort,RZV demonstrated a favorable safety profile in IBD patients,with only mild and self-limiting adverse events,more frequently observed in those receiving biologics. Notably, the very low rate of VZV reactivation(0.7%)over a mean follow-up of 11months confirms the high effectiveness of RZV in this high-risk population.These findings support the integration of RZV into preventive strategies in IBD,particularly before or during immunosuppressive therapy.

BIBLIOGRAPHY

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Table 1

Variable	Overall (420)	UC (n=215)	CD (205)	p
Female	200 (47.6)	100 (46.5)	100 (48.8)	0.713
Male	220 (52.4)	115 (53.5)	105 (51.2)	
Age, median (IQR)	44.00 [30.00, 58.00]	44.00 [32.00, 57.50]	43.00 [30.00, 58.00]	0.579
Baseline therapy				
ADA	77 (18.3)	3 (1.4)	74 (36.1)	<0.001
ADA+USK	3 (0.7)	0 (0.0)	3 (1.5)	
5-ASA	55 (13.1)	46 (21.4)	9 (4.4)	
CCS	5 (1.2)	3 (1.4)	2 (1.0)	
FLG	11 (2.6)	11 (5.1)	0 (0.0)	
GLM	2 (0.5)	2 (0.9)	0 (0.0)	
IFX	67 (16.0)	48 (22.3)	19 (9.3)	
MKZ	3 (0.7)	3 (1.4)	0 (0.0)	
None	41 (9.8)	9 (4.2)	32 (15.6)	
RSZ	9 (2.1)	4 (1.9)	5 (2.4)	
TOFA	4 (1.0)	4 (1.9)	0 (0.0)	
UPA	17 (4.0)	12 (5.6)	5 (2.4)	
USK	64 (15.2)	22 (10.2)	42 (20.5)	
VDZ	62 (14.8)	48 (22.3)	14 (6.8)	
Overall AE				
Yes	220 (52.4)	117 (54.4)	103 (50.2)	0.448
None	200 (47.6)	98 (45.6)	102 (49.8)	
Fatigue				
Yes	67 (16.0)	45 (20.9)	22 (10.7)	0.007
None	353 (84.0)	170 (79.1)	183 (89.3)	
Fever				
Yes	58 (13.8)	33 (15.3)	25 (12.2)	0.427
None	362 (86.2)	182 (84.7)	180 (87.8)	
Injection site pain				
Yes	156 (37.1)	80 (37.2)	76 (37.1)	1.000
None	264 (62.9)	135 (62.8)	129 (62.9)	
Joint pain				
Yes	36 (8.6)	22 (10.2)	14 (6.8)	0.284
None	384 (91.4)	193 (89.8)	191 (93.2)	
Rush				
Yes	9 (2.1)	2 (0.9)	1 (0.5)	1.0
None	411 (97.9)	213 (99.1)	204 (99.5)	
VZV reactivation				
Yes	3 (0.7)	4 (1.9)	2 (1.0)	0.724
None	417 (99.63)	211 (98.1)	203 (99.0)	