ueg week VIRTUAL 2020

SHEBA Tel HaShomer City of Health

October 11–13
ueg.eu

# Effectiveness of third-class biologic treatment in Crohn's disease: a multi-center retrospective cohort study

*Ahmad Albshesh [1], Joshua Taylor[2], Carla Marinelli[3], Marie Truyens[4], Alessandro Armuzzi[5], Davide G. Ribaldone[6], Ariella Bar-Gil Shitrit[7], Morine Fibelman[8], Pauliina Molander[9], Claire Liefferinckx10, Stephane Nancy[11], Mohamed Korani[12], Mariann Rutka [13], Borja Otero-Alvarin[14], Viktor Domislovic[15], Gerard Suris[16], Carl Eriksson[17], Catarina Alves[18], Afroditi Mpitouli[19], Caroline di Jiang20, Katja tepes[21], Marina Coletta[22], Kalliopi Foteinogiannopoulou[23], Javier Gisber[24], Hadar Amir-Barak [25], Mohamed Attauabi [26], Waqqas Afif[2], Edoardo V. Savarino[3], Triana Lobaton[4], Daniela Pugliese[5], Nitsan Maharshak[8], Anneline Cremer[10], Jimmy K. Limdi[12], Tamás Molnár[13], Manuel Barreiro-de Acosta[14], Zeljko Krznaric[15], Fernando Magro[18], Konstantinos Karmiris[19], Tim Raine[20], David Drobne[21], Ioannis Koutroubakis[23], Maria chaparro sanchez[24], Henit Yanai [25], Johan Burisch[26] *Uri Kopylov[1]

1-Department of Gastroenterology, Sheba Medical Center, Tel Hashomer, Israel, Sackler School of Medicine, Tel- Aviv University, Tel-Aviv, Israel, 2- Department of Gastroenterology, Montreal General Hospital, Quebec, Canada, 3- Division of Gastroenterology, Department of Surgery, Oncology and Gastroenterology, University of Padua, Padua, Italy, 4- Department of Gastroenterology, IBD Unit, Ghent University Hospital, Ghent, Belgium,5- IBD Unit Presidio Columbus, Fondazione Policlinico Universitario A. Gemelli IRCCS, Università Cattolica del Sacro Cuore, Roma Italy, 6- Department of Medical Sciences, Division of Gastroenterology, University of Turin, Turin, Italy ,7-Digestive Diseases Institute, Shaare Zedek Medical Center, Jerusalem, Israel, 8- Department of Gastroenterology and Liver Diseases, Tel Aviv Medical Center, Sackler Faculty of Medicine, Tel- Aviv University, Tel-Aviv, Israel,9- Abdominal Center, Gastroenterology, Helsinki University Hospital, Helsinki, Finland, 10- Department of Gastroenterology, Hôpital Erasme, Brussels, Belgium, 11- Department of Gastroenterology, Hospices Civils de Lyon, University Claude Bernard Lyon and INSERM, Lyon, France, 12- Division of Gastroenterology, The Pennine Acute Hospitals NHS Trust, Manchester, M8 6RB UK, Manchester Academic Health Sciences, University of Manchester, Manchester, UK, 13- First Department of Medicine, University of Szeged, Szeged, Hungary, 14- IBD Unit, Gastroenterology Department, University Hospital of Santiago de Compostela, Spain,15- Department of Gastroenterology, Hepatology, and Nutrition, University Hospital Centre Zagreb, Croatia , 16- Digestive System Service, Bellvitge University Hospital, Catalan Institute of Health, Barcelona, Spain , 17- Department of Gastroenterology, Faculty of Medicine and Health, Örebro University, Örebro, Sweden 18- Department of Gastroenterology, Centro Hospitalar São João, Porto, Portugal, 19- Department of Gastroenterology, Venizeleion General Hospital, Heraklion, Crete, Greece,20- Department of Gastroenterology, Addenbrooke's Hospital, University of Cambridge, Cambridge, UK , 21- Department of Gastroenterology, Ljubljana University Medical Centre, Slovenia,22- Gastroenterology and Endoscopy Un V it, Department of Pathophysiology and Transplantation, Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Università Degli Studi di Milano, Milan, Italy, 23- Department of Gastroenterology, University Hospital of Heraklion, Crete, Greece, 24- Hospital Universitario de La Princesa, C/Diego de León 62, 28006, Madrid, Spain, 25- Department of Gastroenterology and Liver Diseases, Rabin Medical Center, Beilinson Campus, Petah Tikva, 26- Department of Gastroenterology, North Zealand Hospital, University of Copenhagen, Copenhagen, Denmark

## Background:

Multiple studies described the effectiveness of ustekinumab (UST) and vedolizumab (VDZ) in CD patients failing anti-TNFs. However, the effectiveness of VDZ or UST as a third-class biologic has not yet been described.

## Aim:

We aim to investigate and compare the effectiveness of VDZ and UST as a third-class biologic in patients with CD.

## Methods

This was a retrospective multicenter cohort study. We included CD patients who received three different classes of biological. The primary outcome was clinical response (≥3 reduction in Harvey-Bradshaw Index (HBI)) at week 16, and secondary outcomes were clinical remission (HBI < 4), C-reactive protein (CRP)-normalization, adverse events, corticosteroid-free remission, and response at both week 16 and 52.

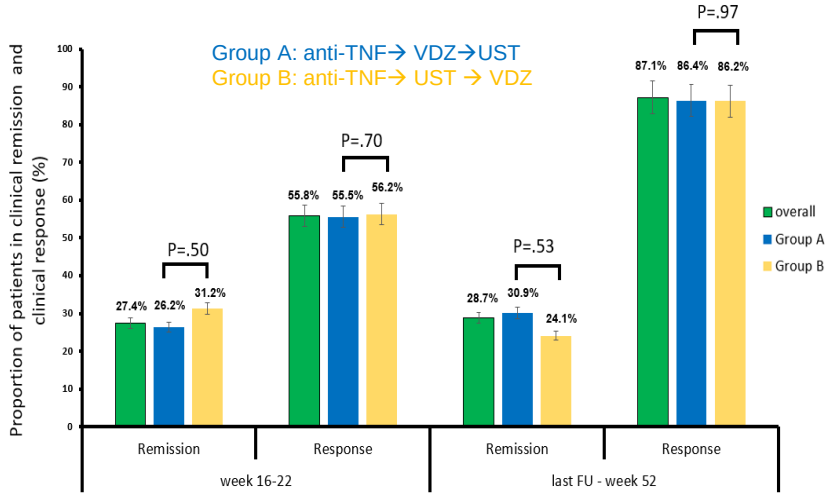
## Results:

| | over all number | Group A | Group B | P-value |
|---|---|---|---|---|
| Patients number, N (%) | 204 | 156 (76.47%) | (23.52%) 48 | P < 0.0001 |
| Age , median (IQR) | (32-53) 41.5 | 32-) 43.6 (52.7 | (31-54.7) 43.5 | P = 0.9650 |
| Gender—male, N (%) | (47.05%) 96 | (47.43%) 74 | (45.83%) 22 | P = 0.8458 |
| Disease duration , median (IQR) | (10.25-22) 16 | 10-) 15 (20.75 | 11-) 16.5 (25.75 | P = 0.1370 |
| Location (N,%) | | | | |
| ileum | (22.54%) 46 | (21.7%) 34 | (% 25)12 | P = 0.6424 |
| colon | (20.09%) 41 | (23.07%)36 | (10.14%) 5 | P = 0.0627 |
| ileocolonic | (52.45%) 107 | (50%) 78 | (60.4%) 29 | P = 0.2079 |

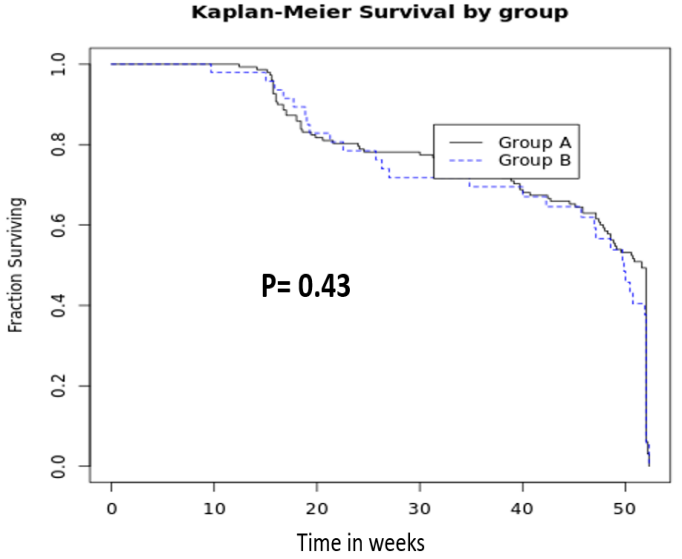
**At week 16-22:** clinical response : 87/156(55.5%) and 27/48 (56.2) (p=0.70).
clinical remission: 41 /156 (26.2%) and 15 /48 (31.2%) (p=0.50).
in groups A and B respectively

**At week 52**; clinical response : 89/103 (86.4%) patients, and 25/29 (86.2%) (p=0.9)
clinical remission; 31/103 (30%) and 7/29 (24.1%) (p=0.5)
in groups A and B respectively

**Treatment discontinued** : 26/156 (17.3%) in group A and 9/48 (18.75%) in group B.
The mean reason for discontinuation of treatment was clinical failure.






## Conclusion:

**The current study demonstrates that administering a third-class biological therapy is effective in more than half of the patients with CD, who have already failed two classes of biological drugs. No difference in effectiveness was detected between VDZ and UST as a 3rd class agent.**