Validation of Primary and Secondary ICD-9-CM codes for Upper Gastrointestinal Complications in Friuli Venezia Giulia, Italy

Federica Pisa, Daniela Drigo, Nuria Riera-Guardia, Jordi Castellsague, Valentina Rosolen, Elena Cignan, Francesca Tosolini, Lori Zanier, Susana Perez-Gutthann, Fabio Barbone

1 Institute of Hygiene and Clinical Epidemiology, University Hospital of Udine, Italy; 2 RTI Health Solutions, Barcelona, Spain; 3 Servizio di Epidemiologia, Direzione Centrale della Salute, Integrazione Socio Sanitaria e Politiche Sociali, Regione Friuli Venezia Giulia, Udine; 4 Servizio Assistenza Farmaceutica, Direzione Centrale della Salute, Integrazione Socio Sanitaria e Politiche Sociali, Regione Friuli Venezia Giulia, Trieste, Italy

BACKGROUND AND OBJECTIVE

Most validation studies of diagnostic codes in secondary position are based on a retrospective chart review. To date, no studies have compared site-specific UGICs among studies using secondary discharge codes. This study aimed to validate the primary and secondary ICD-9-CM discharge codes for UGICs in a population-based cohort study in Friuli Venezia Giulia (FVG), northern Italy with 1.2 million inhabitants.

METHODS

Details on Patients: 
- General population in the region of FVG for at least one year in residence.
- Case and control databases: Patient Identification, Outpatient Source Population.

Data Sources: 
- Key databases: Patient Identification, Outpatient Source Population, and Hospital Medical Charts.

Study Design: 
- Retrospective population-based cohort and nested case-control study.

Exclusion Criteria: 
- All residents in FVG for at least one year prescribed an NSAID between January 1, 2001, and

Inclusion Criteria: 
- Accuracy of outcome measurement in northern Italy with 1.2 million inhabitants.

RESULTS

• PPVs were above 90% for site-specific codes in primary position 531 (gastric ulcer), 532 (duodenal ulcer), and 534 (gastrojejunal ulcer), and 40.2% for nonspecific code 578 (gastrointestinal hemorrhage) in primary position.

• Secondary codes generally show low PPVs (from 40.1% of codes 531 and 532 based on the abstraction of a random sample of 458 charts).

• A total of 449 charts (98.0%) were obtained; 156 were confirmed as cases of UGIC, while giving the research partners scientific independence, including publication of results.

CONCLUSIONS

- The validation of a random sample of secondary codes increased the ascertainment of cases of UGICs by 15.6%.

- Incidence rates estimated without including confirmed cases identified with secondary position underestimated the true incidence of UGICs.

REFERENCES


- Ethical and Scientific Review and Funding Source

The study was approved by the RTI International institutional review board. The study was funded and monitored through the centers of hospital databases in the FVG region.

The study was conducted under Good Pharmacovigilance Practices (GVP). The study was conducted in accordance with the Declaration of Helsinki. The ICH regulatory requirement, the good clinical practice (GCP) for clinical studies, and all applicable local regulations.

Informed consent was obtained from all participants in the study, and ethics committee was involved in the design of the study as well as the execution of the study.

The financial sponsor of this study was Helsinn Healthcare S.A., manufacturer of nimesulide. The study complied with the International Conference on Harmonisation (ICH) guidelines for Good Clinical Practice (ICH-GCP). The study was conducted in accordance with the requirements of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The study was conducted in accordance with the requirements of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

CONTACT INFORMATION

Federica Pisa, MD, PhD University Hospital of Udine, Italy, Instituto Clinici di Virologia, Udine Phone: +39 0432 308241 Fax: +39 0432 308200 Email: federica.pisa@udine.it Presented at: 21st International Conference on Pharmacoepidemiology & Therapeutics Risk Management, Angeles, Philippines Chicago, IL, United States