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Evaluation of intravenous immunoglobulin (IVIG) utilization after the implementation of indication and dosing protocol at a community health system.

Nicholas Buttermore
Parkview Health, nicholas.buttermore@parkview.com

Jamie Gaul PharmD, BCPS
Parkview Health, jamie.gaul@parkview.com

Kate Oetting

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Nicholas J. Buttermore, PharmD Candidate[1,2], Jamie Gaul, PharmD, BCPS[1], Kate Oetting, PharmD Candidate[3]

1. Parkview Regional Medical Center, Fort Wayne, IN 2. Manchester University College of Pharmacy, Fort Wayne, IN 3. Purdue University, West Lafayette, IN

OBJECTIVE

- This study was conducted to evaluate the patient landscape of IVIG use within our community health system, both before and after protocol implementation. Our goals were to identify potential changes with the indication for use along with any prescribed dosing decreases while under protocol.

BACKGROUND

- Intravenous Immunoglobulin (IVIG) serves as a therapeutic option for a variety of disease states which stem from immunodeficiency or inflammatory reactions.[1]
- IVIG currently holds 7 different FDA-approved indications; however, there are many off-label uses of IVIG with varying levels of clinical evidence and proven efficacy.[1]
- Standard dosing of IVIG varies by indication, ranging from 0.2-2 g/kg. Dosing weight for IVIG has traditionally been actual body weight (ABW); however, ideal body weight (IBW) dosing has demonstrated non-inferiority.[1]
- The U.S. market currently reports over 5.9 billion dollars in total cost from IVIG utilization with projections of an annual 6.8% increase in cost through 2028.[2]
- With IVIG shortages as a continual concern, IBW IVIG dosing restrictions serve as a viable solution to minimize over utilization, immunoglobulin waste, and inflated market demands.

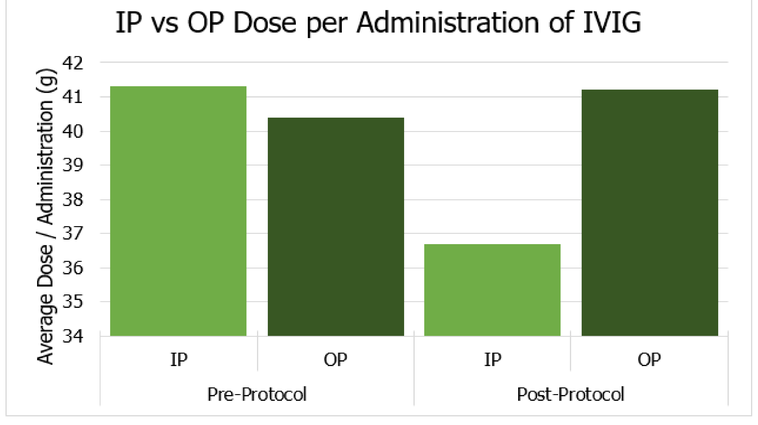
METHODS

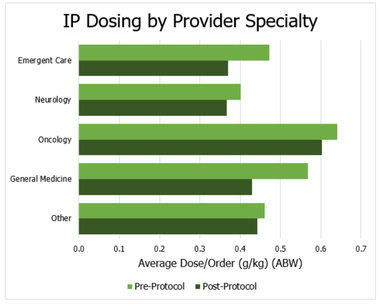
- Retrospective, system-wide, cohort study comparing two separate 18-month periods spanning from January 2018 to June 2019 and July 2019 to December 2020.
- Parkview Health System implemented a restrictive dosing and indication protocol for use of IVIG starting in July of 2019.
- The patient population consisted of both inpatient (IP) and outpatient (OP) hospital-based infusion clinics who had EHR documentation of IVIG administrations.
- The first group represented standard pre-protocol utilization of IVIG (pre-protocol), whereas the second group was dictated by our hospital's restrictive use policy (post-protocol).
- The following data was obtained for each patient encounter: age, height, weight, gender, associated diagnosis, and total dose/day.
- Patients were additionally grouped by inpatient or outpatient setting, ordering provider specialties, and grouped diagnoses.
- Diagnoses were grouped into the following categories: primary immunodeficiency, other immunodeficiency, neuroimmunologic disorders, neuromuscular junction syndromes, immune thrombocytopenia, non-immune thrombocytopenia, autoimmune skin conditions, miscellaneous, other autoimmune diseases, and infection-related diseases.
- All data was extracted from the electronic health record (EHR) and manually validated. The data was evaluated via descriptive statistics.

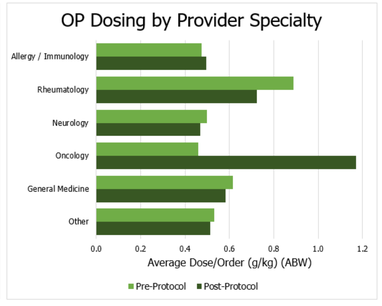
RESULTS

Subgroup	Pre-Protocol	Post-Protocol
	by no. of administrations (total = 2660)	
Number of Patients	182	182
Number of Administrations	1206	1454
Age (yrs) (mean ± SD)	61.8 ± 15.2	60.7 ± 15.6
Female	801 (66.4%)	917 (63.1%)
Height (cm) (mean ± SD)	166.1 ± 13.0	168.8 ± 11.5
Actual Body Weight (kg) (mean ± SD)	82.2 ± 22.5	83.1 ± 21.75
Median Admin/Patient (Range)	4 (1 - 57)	5 (1 - 75)
Outpatient (OP)	865 (71.7%)	1133 (77.9%)
Inpatient (IP)	341 (28.3%)	321 (22.1%)
Total Grams IVIG (g)	49,068	58,434
Diagnosis*		
Primary Immunodeficiency	511 (42.4%)	560 (38.5%)
Neuroimmunologic Disorders	437 (36.2%)	553 (38.0%)
Neuromuscular Junction Syndromes	95 (7.9%)	159 (10.9%)
Immune Thrombocytopenia	106 (8.8%)	48 (3.3%)
Non-immune Thrombocytopenia	18 (1.5%)	26 (1.8%)
Autoimmune Skin Conditions	96 (8.0%)	96 (6.6%)
Infection-Related Diseases	40 (3.3%)	10 (0.7%)
Other Immunodeficiency	178 (14.8%)	71 (4.9%)

*Patient diagnoses were often grouped with >1 diagnosis per patient







RESULTS

- Neurology and oncology provider specialties saw the greatest number of patient administrations in the IP setting (pre: 161, 98 post: 149, 95) respectively.
- Neurology and allergy/immunology provider specialties saw the greatest number of patient administrations in the OP setting (pre: 247, 397 post: 436, 473) respectively.
- Pricing was evaluated using a standardized product (Gammagard 10%) due to a wide variation of IVIG brand utilization during the post-protocol product shortage.
- Average Wholesaler Price (AWP) per gram of 100 mL of Gammagard 10% was $239.24 as of August 2021.[3]
- Basing the AWP price for Gammagard 10% on observed dosing decreases in the inpatient setting, potential cost savings per administered IVIG dose are $1,100.50.
- This value is highly dependent upon location, provider adherence to dosing and prescribing recommendations, and indication of patients.

DISCUSSION & CONCLUSIONS

- We expected to observe a decrease in total grams of IVIG utilization between pre- and post-protocol populations but saw an increase in overall use and administrations.
- The overall average dose was slightly lower but was more prominent after separating inpatient, acute use from outpatient, chronic use.
- Due to limitations with defining a single, specific associated diagnosis or indication, no specific conclusions can be drawn on potential impact to specific disease states or areas.
- Chronic-use IVIG patients are typically seen in the OP setting and tend to be stable on a previously determined regimen, so dose decreases under new dosing protocols are unlikely in the OP setting. This was confirmed in our review as the average total dose was similar in the pre- and post-protocol outpatient doses.
- Best application is in the inpatient setting with greater chance for protocol adherence/implementation.
- General medicine, oncology, neurology, and emergent care are locations with the greatest utilization of IVIG and greatest opportunity for dosing optimization.
- The use of IVIG restriction protocols has the potential for major cost-savings and the avoidance of overutilization specifically in the inpatient setting; however, success is highly dependent upon provider dosing adjustments and adherence.

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Disclosure

The authors of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation:
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