MEDICAL, PHARMACY, AND SICK LEAVE COSTS FOR CONSTIPATIONAND FOR IRRITABLE BOWEL SYNDROME WITH CONSTIPATION IN THE 6 MONTHS BEFORE AND AFTER DIAGNOSIS: An Employer Perspective

Nathan L. Kleinman, PhD[1], Richard A. Brook, MS[2]*, Arthur K. Melkonian, MD, Robert W. Baran, PharmD[3], and Nicholas J. Talley, M.D., Ph.D.[4]

[1]Research Services, HCMS, Cheyenne, WY; [2]Retrospective Analysis, The JeSTARx Group, Newfoundland, NJ, United States; [3]Medical Outcomes Research, Takeda Global Research and Development, Deerfield, IL and; [4]Chairman of Medicine, Mayo Clinic, Jacksonville, FL

Introduction

- Constipation and Irritable Bowel Syndrome with Constipation (IBS-C) impose substantial direct and indirect costs on the healthcare system and impair health-related quality-of-life.[1-5]
- Recent research demonstrates:
  - The projected total incremental direct costs for constipation in all US employees is $3.12 billion per year.[3]
  - The total direct costs in the US for healthcare encounters where constipation was the primary diagnosis exceeded $235 million annually.[4]
  - Patients presenting for GI complaints within the Group Health Cooperative health system incurred annual mean costs of $5049 for IBS and $7522 for constipation.[5]
- Additional studies are needed to quantify the comparative costs of constipation and IBS-C.

Similarities in costs for constipation and IBS-C suggest that both have a similar impact on the healthcare system.

AIM

- To examine the comparative direct and indirect cost burden of constipation and IBS+C for insured employees.

Methods

- A retrospective analysis was performed on data extracted from the Human Capital Management Services (HCMS) Research Reference Database consisting of approximately 510,000 employees representative of the US Employed Civilian Labor Force (2004).
- Patient healthcare claims from 1/1/2001 to 6/30/2006 were included in the analysis.
- Anonymity of person-level data was maintained according to the Health Insurance Portability and Accountability Act guidelines.
- Healthcare for the entire employee cohort was provided through managed care plans contracted by respective employers.
- International Classification of Diseases v.9 (ICD-9) codes in claims records were used to identify employees with primary, secondary, or tertiary diagnoses of constipation:
  - 564.0 (Constipation)
  - 564.00 (Unspecified)
  - 564.01 (Slow Transit)
  - 564.09 (Other)
- ICD-9 codes in claims records were also used to identify employees with primary, secondary, or tertiary diagnoses of IBS:
  - 564.1 (IBS)
- IBS-C was represented by the condition where an ICD-9 for Constipation plus an ICD-9 for IBS were both present in the employee's claims records (IBS+C).
- Two cohorts were created for comparison purposes:
  - Constipation (C) cohort:
    - Employees with at least one record of constipation diagnosis (constipation ICD-9 codes listed above) and no ICD-9 for IBS.
  - Irritable Bowel Syndrome plus constipation (IBS+C) cohort: Employees with at least one record of constipation diagnosis (constipation ICD-9 codes listed above) and at least one record of IBS diagnosis (ICD-9 for IBS).
- The index date in the C cohort was defined as the date of first diagnosis of constipation during 2001 or later as noted by ICD-9 code in the claims record.
- The index date in the IBS+C cohort was defined as the date of first diagnosis of IBS during 2001 or later as noted by ICD-9 code in the claims record.
- C and IBS+C cohorts were compared over the six months preceding and following the employee's "index date."
- Employees were required to be continuously employed and eligible for health benefits for at least six months before and after their index date.
- The following outcomes measures were compared between C and IBSC cohorts:
  - Per Member Per Month (PMPM) costs:
    - Direct Medical
    - Prescription drug (Rx) costs, and
    - Sick Leave
    - Semi-Annual (6 month) sick leave absence days.

Statistical Analysis

- For each employee in the IBS+C cohort, 5 C employees were matched using logistic regression and propensity scores for age, tenure (years with current employer), sex, marital status, race, exempt/nonexempt status (exempt employees are not paid on an hourly basis and are not paid for overtime work), full-time/part-time status, salary, Charlson Comorbidity Index score,[6] region (defined by first digit of employee's postal zip code), and existence of a direct medical claim.
- All costs were adjusted to 2006 dollars.
- Significance was measured by t-tests at $P \leq 0.05$
- Differences were explored for significance:
  - Between cohorts (C vs. IBS+C), for the:
    - 6 months prior to the index date,
    - 6 months after the index date, and
    - change (after – prior)
  - Within cohorts (6 months prior to index date vs. 6 months after index date)

Results

- Data were available for 309 **IBS+C** persons with constipation and 1,545 propensity-score matched C persons **(Table 1)**.
  - Following propensity score matching, no significant differences were observed between cohorts.
- Comparisons of PMPM costs **(Table 2)**:
  - Between cohorts:
    - Prescription drug costs were $26 higher (ƒ I 0.05) PMPM for the IBS+C cohort than the C cohort.
    - All other between group comparisons were non-significant (P>0.05)
  - Within cohorts:
    - Prescription drug costs were significantly increased (ƒ I 05) from the 6-months before to the 6-months after diagnosis for bothIBS+C and C cohorts.
    - Direct medical costs were significantly increased (ƒ I 05) from the 6-months before to the 6-months after diagnosis for bothIBS+C and C cohorts.
- Comparisons of Sick Leave time **(Figure 1)**:
  - Between cohorts:
    - Employees in the IBS+C cohort had 1.3 more sick leave days on average than employees in the C cohort (P≤0.05) during the 6-months after diagnosis.
    - All other between comparisons were non-significant (P>0.05)
  - Within cohorts
    - Sick leave time increased from before diagnosis to after diagnosis in both IBS+C and C cohorts; however, no within group differences were significant

Limitations

- Both Constipation and IBS+C may be underreported in healthcare databases due to ICD-9 coding anomalies.
- Cohorts were composed of continuously employed subjects, suggesting a relatively healthy population for analysis and the potential for underestimation of disease burden.
- The clinical diagnosis of IBS-C must be inferred from the operational definition of the IBS+C cohort.

Summary and Conclusions

- Both Constipation and IBS+C are associated with substantial direct cost (burden) of illness, which can be a large financial liability to employers.
- The only cost difference between groups was for prescription drugs which may be due to medications which are uniquely indicated for IBS+C.
- In the 6-months after diagnosis:
  - Costs increased significantly for both groups.
  - Absenteeism was higher for IBS+C.
- These results indicate an opportunity for improved management of patients with both constipation and IBS-C, which may result in reduced costs from an employer perspective.

TABLE 1: Descriptive Statistics for Matched Cohorts of Employees with Constipation vs. Employees with IBS+C

Characteristic	Employees with Constipation N	Employees with Constipation Mean [S.E]	Employees with IBS+C N	Employees with IBS+C Mean [S.E,]	Difference in Means
Age (at index date), years	1,545	41.00 [0.27]	309	40.20 [0.59]	-0.80
Length of time working for employer (Tenure, at index date), years	1,545	8.71 [0.20]	309	8.45 [0.44]	-0.27
Female, %	1,545	73.8%	309	77.3%	3.6%
Married, %	1,411	50.4%	285	48.8%	-1.6%
Race:	1,187		239		
White, %		59.9%		62.8%	2.9%
Black, %		13.7%		12.1%	-1.6%
Hispanic, %		14.8%		13.4%	-1.4%
Exempt, %	1,545	30.4%	309	33.0%	2.6%
Full Time, %	1,545	94.1%	309	94.8%	0.7%
Annual Salary, US $	1,545	$48,900 [$720]	309	$49,676 [$1,513]	$775
Educational Level	253		72		
Less Than High School, %		0.8%		0.0%	-0.8%
High School Diploma or GED, %		41.9%		33.3%	-8.6%
Some College or Trade School, %		12.3%		12.5%	0.2%
Associate's or Trade School Degree, %		3.6%		6.9%	3.4%
Bachelor's Degree, %		29.6%		37.5%	7.9%
Master's Degree or MBA, %		8.7%		9.7%	1.0%
JD (Law Degree) , %		0.4%		0.0%	-0.4%
PhD or MD or PharmD, %		2.8%		0.0%	-2.8%

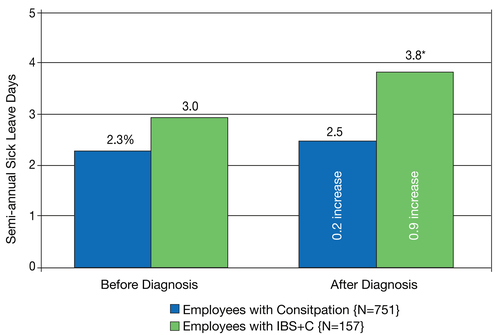
All variable similar (P>0.05)
S.E. = Standard Error

TABLE 2: PER MEMBER PER MONTH HEALTH BENEFIT COSTS PER EMPLOYEE

Per Member Per Month Cost	Employees with Constipation N	Employees with Constipation Adjusted Mean Cost, $ US	Employees with IBS+C N	Employees with IBS+C Adjusted Mean Cost, $ US	Constipation vs. IBS+C Between Cohort Difference in Means, $ US
Before Diagnosis					
Health Care	1,545	450	309	499	-48
Prescription Drug	1,545	88	309	98	-10
Sick Leave	751	68	157	86	-18
Total		606		683	- 76
After Diagnosis					
Health Care	1,545	689	309	623	66
Prescription Drug	1,545	107	309	134	-26†
Sick Leave	751	73	157	106	-33
Total		869		863	7
Change (After-Before)					
Health Care	1,545	238*	309	124*	114
Prescription Drug	1,545	19*	309	36*	-16
Sick Leave	751	5	157	20	-16
Total		262		180	82

† Significant Difference Between cohorts (P≤0.05)
*Significant Change within-cohorts (P≤0.05)

FIGURE 1: COMPARISON OF SEMI-ANNUAL SICK LEAVE DAYS PER EMPLOYEE



References

1 Dennison C, Prasad M, Lloyd A, Bhattacharyya SK, Dhawan R, Coyne K. The health-related quality-of-life and economic burden of constipation. *Pharmacoeconomics.* 2005;23:461-76.

2 Kleinman NL, Brook RA, Melkonian AK, Baran RW. Healthcare Cost Comparisons by Point of Service for Persons With or Without Constipation. *Am J Gastroenterol.* Sep 2006; 101(suppl2):S408.

3 Brook RA, Kleinman NL, Melkonian AK, Baran RW. Cost of Illness for Constipation: Medical, Pharmacy, and Work Absence Costs in Employees With or Without Constipation. *Am J Gastroenterol.* Sep 2006; 101(suppl2):S408.

4 Martin BC, Barghout V, Cerulli A. Direct medical costs of constipation in the United States. Manag Care Interface. 2006 Dec;19(12):43-9.

5 Nyrop KA, Palsson OS, Levy RL, Korff MV, Feld AD, Turner MJ, Whitehead WE. Costs of health care for irritable bowel syndrome, chronic constipation, functional diarrhoea and functional abdominal pain. *Aliment Pharmacol Ther.* 2007 Jul;26(2):237-248

6 Charlson ME, et al. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chronic Dis.* 1987;40:373-83.