Benefits of over-the-counter heartburn medication to consumers and the healthcare system

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Abstract

Objective – A variety of OTC medications for heartburn are available for consumers to treat their symptoms, however, the benefits of these treatments are not widely documented. The objective of this study is to outline and quantify the benefits of OTC heartburn therapy for consumers and the healthcare system in the context of treatment satisfaction and cost savings.

Research design and methods – A representative survey of consumers suffering from heartburn was conducted using NielsenHealth's Heartburn Ailment Panel from Nielsen's HomeScan panel. Costs for OTC and prescription therapy were derived from Nielsen's HomeScan panel and WoltersKluwer's SourceLx annonymized patient level database.

Results – The satisfaction level of consumers suffering from heartburn in the past 12-months using OTC heartburn medications was ~94%. The savings to the healthcare system from the availability of OTC heartburn medications to decrease office visits by consumers is ~$757-million annually. The savings to the consumer in prescription and office visits annually is ~$174.

Conclusions – These findings document OTC heartburn medications provide symptom satisfaction and cost saving benefits to consumers and the healthcare system.

Abbreviations: OTC, over-the-counter medication; WK, WoltersKluwer's SourceLx annonymized patient level database; PPI, Proton Pump Inhibitor; H2, H_2-receptor antagonist; Antacids, products that buffer gastric acid; office visit, physician or healthcare provider visit

Introduction

Heartburn is caused by gastric acid flowing back into the esophagus. Treatment for heartburn includes weight loss, diet, avoiding certain foods, and medications. Today's heartburn medications modes of action either decrease the gastric acid in the stomach or increase the motility of the esophagus. Medications that decrease the gastric acid in the stomach are being considered in this research. The acid reducing medications method to decrease acid is the following: Antacids neutralize acid, H2s decrease the production of acid as an antagonist, and PPI inhibit the release of acid. Because the mode of action of the medications work differently, a variety of options can and do benefit consumers. The benefits of treatment for heartburn include immediate symptom relief in addition to decreasing the risk of long term medical problems. The risk of long term exposure of acid to the esophagus causes ulcers and erosion of the esophagus wall lining. It is widely published that medication treatment for heartburn and GERD decrease the risk of long term medical problems associated with the disease such as esophageal narrowing (stricture), esophageal ulcer, and Barrett's esophagus (a precancerous condition).[2,3,4]

Prevalence of heartburn is high at ~5% of the population. In the US today, ~16M[5,6] individuals are treating for heartburn. Treatment algorithms for heartburn have changed over the past ~15 years as the evolution of treatments has expanded from prescription to over-the-counter. Medications with aluminum-containing, magnesium-containing, calcium-containing, or bismuth-containing active ingredients, among others, have existed for a number of decades. In the early 1990s, these were joined by H2s switched to OTC from prescription status, followed by a PPI, Prilosec (omeprazole) in September 2003. In 2009, additional PPI products are being considered by the FDA[7] for OTC availability including Zegerid (omeprazole/sodium bicarbonate) and Prevacid (lansoprazole), both currently prescription products.

The availability of heartburn medications over-the-counter has increased the utilization of treatment by consumers and provides benefits to the consumer and the healthcare system. This research seeks to quantify the benefits of over-the-counter medications to the consumer and the healthcare system. This research is focused on the benefits of symptom relief satisfaction and cost savings of over-the-counter medication availability.

Research design and methods

Design

Survey

The survey was conducted by Nielsen of consumers suffering from heartburn. The consumers surveyed are part of Nielsen's Homescan panel which is a representative sample of US households. Individuals in the Homescan panel are surveyed annually by NielsenHealth to determine the household and individuals in the household suffering from a variety of ailments. Individuals which responded as heartburn sufferers were further surveyed by NielsenHealth as part of an annual Heartburn Ailment Patient Facts survey. The results of the Patient Facts survey were which were utilized for this research.

Savings

The cost comparisons of prescription and over-the-counter treatments were utilized from two different sources. Over-the-counter medication costs were obtained from the average costs of therapy from Nielsen's HomeScan purchase panel which scans all consumer products purchased by a household. Prescription medication costs were obtained from WoltersKluwer SourceLx which captures prescription claims in the US.

Databases

Nielsen HomeScan - Nielsen's Homescan data are collected from a longitudinal stratified random sample of 125,000 households representative of the continental U.S. Each household provides continuous information around purchasing behavior collected with an in-home scanning device.

NielsenHealth Ailment Panel - The 32 NielsenHealth Ailment Panels are a subset of the Nielsen Homescan panel and consist of 110,000 individuals in 65,000 Homescan households providing insights on their medical condition, with patient facts such as ailment severity, treatment regimen, influencers, age, gender, and demographics.

NielsenHealth Heartburn Ailment Panel - The Heartburn Ailment Panel consists of households with individuals claiming to be heartburn sufferers. Patient facts including ailment severity, treatment regimen and influencers are crossed with OTC purchase behavior from Homescan to understand variations across different sufferer segments. The panel also contains all of the rich demographic attributes available through Homescan for each household to allow for further segmentation. The panel contains ~22,000 households and ~25,000 individuals suffering from heartburn.

WoltersKluwer SourceLx - Source® Lx integrates health care claims data from physician practices, pharmacies, and hospitals for more than half of the U.S. population for the broadest, most timely view of healthcare delivery, cost, and usage patterns.

Methods

Survey

Patient satisfaction was the key theme utilized to quantify the benefits of treatment for consumers utilizing over-the-counter heartburn therapies. The satisfaction levels were segmented into satisfied, neither satisfied/unsatisfied, and unsatisfied. Treatment choices were at the product level but aggregated for this research to the medication classes; PPI, H2, and Antacid/GI agents. The survey measured satisfaction across the following:

- Patients' satisfaction of treatment,
- prescription utilization,
- frequency of symptoms,
- severity and bothersome levels of symptoms,
- duration of symptoms,
- occurrence of symptoms,
- symptom triggers,
- frequency of treatment,
- discussion with physician specialty, recommendations, and diagnosis,
- influencers by healthcare coverage

Savings

Healthcare savings from over-the-counter therapy were estimated and projected by the number of office visits not experienced due to OTC therapy. The savings were derived by determining the ratio of office visits of treating patients with satisfied OTC vs. non-OTC prescription therapy patients. The ratio difference of non-OTC treating patients was applied to the satisfied patients to determine the current annual visits saved by over-the-counter therapy. An average cost for office visit of $121[8] was used to quantify for healthcare savings.

Consumer savings were estimated by the decreased rate of office visit and OTC medication vs. prescription costs. The average rate of office visit for a satisfied OTC patient is 1.31 per year, whereas, for a non-OTC prescription treating patients the rate is 1.85. Furthermore, we refined the rate of office visits further by defining the rate of visits in which a consumer discussed their heartburn symptoms; which was 39% vs.

63% for OTC vs. prescription users respectively. This increased rate of office visit was utilized to quantify the rate of office visits per consumer per year.

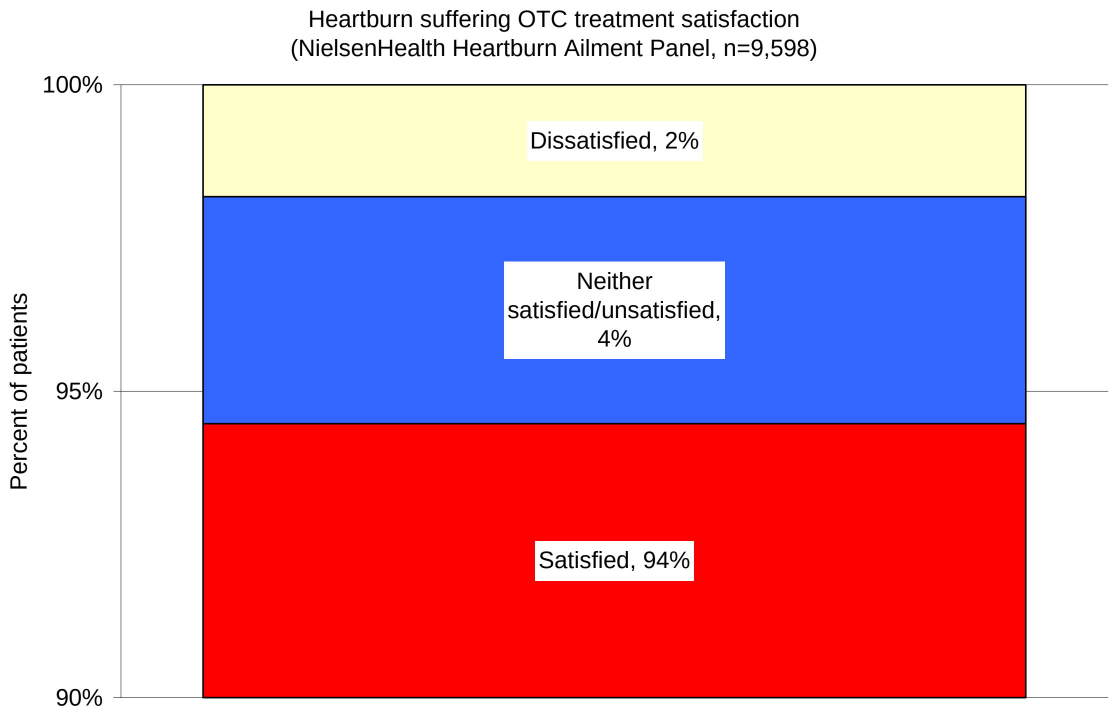
Consumer medication savings were derived by comparing the out-of-pocket cost for OTC vs. prescription medications for the overall class then comparing by PPI and H2. Antacids and other GI motility agents did not have comparable prescription and OTC comparators. Presented in this research are savings for the overall heartburn treatment class.

Results

The NielsenHealth Heartburn Ailment Panel Patient Facts survey contained 17,412 individuals suffering from heartburn during the past 12-months. Individuals utilizing OTC only therapy included 9,598 or 55%.

Satisfaction of OTC therapy - The satisfaction level of consumers suffering from heartburn in the past 12-months using OTC heartburn medications was high at 94%.

Exhibit: Satisfaction of OTC therapy chart



Frequency of symptoms and satisfaction levels with OTC – Not surprising, the consumers experiencing symptoms 4-7 times/week are less satisfied with treatment, but still 92% are satisfied. Consumers experiencing symptoms 1-3 times/week and 3 times/month or less are satisfied at 94% and 96% respectively.

Severity and satisfaction levels with OTC– The severe patients have the most variance of satisfaction as only 85% of these OTC sufferers are satisfied. However, this group is only 4% of the total heartburn sufferer population with moderate (43%) and mild (53%) of sufferers with similar levels of satisfaction at 94% and 96%, respectively.

Symptom occurrence – The time of day of symptom occurrence does not appear to be a driver of satisfaction, however, the rate of evening and both (day and evening) patients is ~91% of consumers; with ~35% evening only.

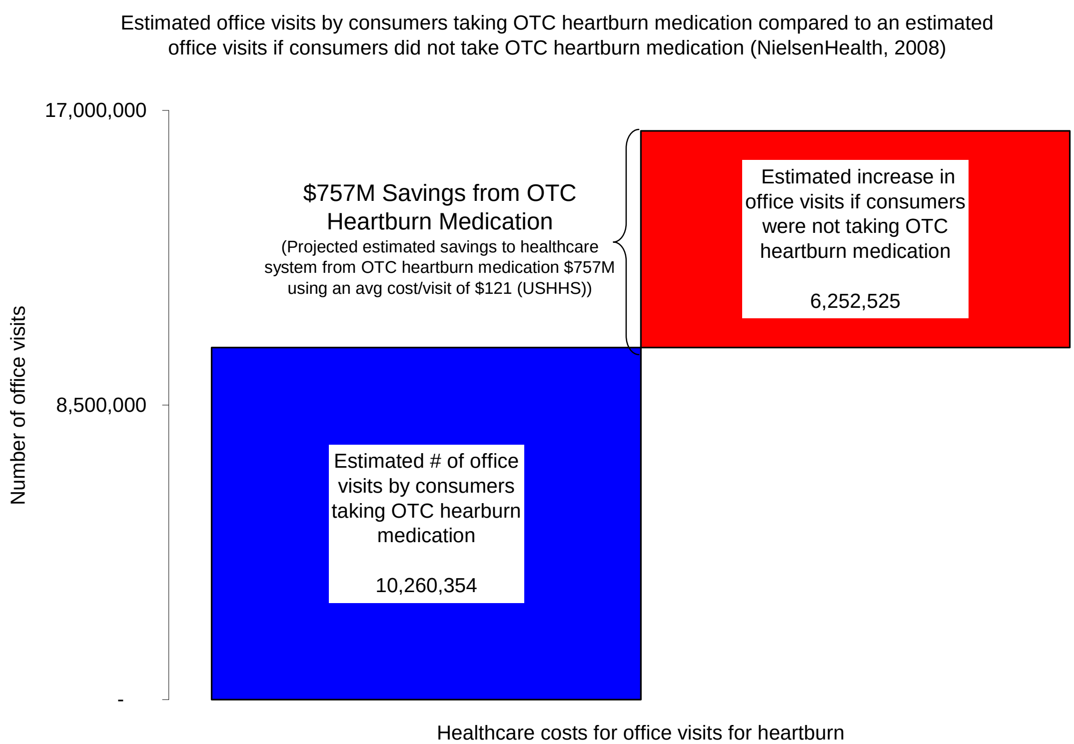
Physician or healthcare provider discussion – Of interest, ~61% of patients have not discussed their symptoms with their physicians. This finding supports that the majority of patients are able to recognize heartburn symptoms without seeing a physician. Most importantly, the patients not seeing a physician were 95% satisfied with their OTC therapy. In summary, these patients recognized their symptoms, diagnosed themselves, treated themselves with OTC, and were satisfied.

Of the 39% that did discuss their symptoms with their physician, ~44% were recommended an over-the-counter medication and 13% a prescription. The remaining patients received recommendations for diet, weight loss, quit smoking, or other.

Diagnosis and satisfaction with OTC – Satisfaction levels with OTC therapy for diagnosed heartburn (30%) vs. GERD (26%) patients were similar at 96% and 94%, respectively. This could suggest further opportunity for more severely suffering patients diagnosed with GERD could be treated with over-the-counter medications; additional research by manufacturers would be required to obtain an indication.

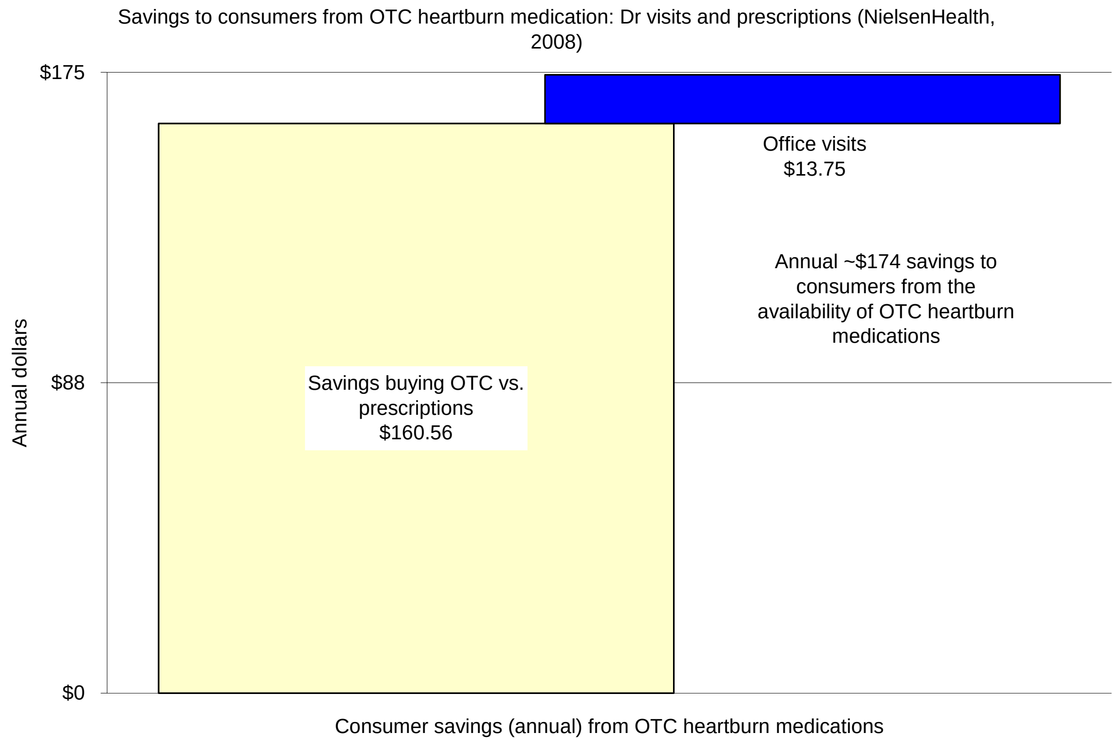
Healthcare savings – Healthcare savings were derived by determining the rate of office visit in which a consumer discussed their heartburn symptoms for OTC only treating patients vs. prescription only treating patients. The rate of discussion was 39% vs. 63% for OTC vs. prescription treating patients; a ratio of 1.62 greater for prescription patients. We then projected the increase in discussion in visits which would have occurred if patients were not taking OTC based on this ratio. Based on this ratio, the savings in office visit discussion for those patients taking OTC is ~6M office visits. The increase in office visit discussion in dollars at ~$121 per office visit is $757M; [$757M = 6.253M office visits x $121 cost per office visit]. Therefore, the estimated savings OTC heartburn medications provide in office visit discussions is ~$757M.

Exhibit: Healthcare saving chart



Consumer savings – Overall, OTC therapy saves consumers ~$174 in office visits and medication.

Exhibit: Consumer savings chart



Consumer healthcare savings – Healthcare savings for the consumer in office visits were derived by determining the rate of increased office visits if not taking OTC therapy. Increased office visits were derived by using the ratio of increased office visits on an annual basis for OTC treating patients vs. prescription treating patients. The average office visits for OTC and prescription was 1.31 to 1.86 respectively; a ratio of 0.55. We multiplied the ratio of 0.55 by the average out of pocket cost for an office visit of $25 to dollarize healthcare savings of $13.75.

Consumer medication savings – Medication savings for the consumer using OTC vs. prescription were compared overall. We find overall patients save on medications ~$160.56 annually; this assumes patients complied with indicated use requiring 12-monthly purchases.

Exhibit: Healthcare savings table

Description		Metrics					Source
US population		303,000,000					US Gov
Persons per HH		2.60					Nielsen
Households		116,538,462					Nielsen
HH with heartburn		15%					NielsenHealth Ailment Panel
HH with heartburn		17,480,769					NielsenHealth Ailment Panel
HH with heartburn		12,984					NielsenHealth Ailment Panel
Individuals per HH with heartburn		14,460					NielsenHealth Ailment Panel
Indivduals per HH heartburn		1.11					NielsenHealth Ailment Panel
Individuals treating		11,908					NielsenHealth Ailment Panel
Individuals treating		82%					NielsenHealth Ailment Panel
Indivduals treating for heartburn		16,032,116					NielsenHealth Ailment Panel
Average physician visits/year		1.63					NielsenHealth Ailment Panel
OTC Treaters, avg Dr. visits/year		1.31					NielsenHealth Ailment Panel
Rx Treaters,avg Dr. visits/year		1.86					NielsenHealth Ailment Panel
OTC vs.Rx avg Dr visits/year		0.55					NielsenHealth Ailment Panel
OTC Rate of visits mentioned symptoms		39%					NielsenHealth Ailment Panel
Rx Rate of visits mentioning symptoms		63%					NielsenHealth Ailment Panel
Rx Ratio of visits mentioning heartburn		1.62					NielsenHealth Ailment Panel
Average cost per visit	$	121.00					US HHS, AMA
Average physician visit copay	$	25.00					US HHS, AMA
Savings for healthcare and consumer		Savings					Source
Hearburn consumers seeing a Dr.							
Taking OTC		10,160,354					NielsenHealth Ailment Panel
If not taking OTC		6,252,525					NielsenHealth Ailment Panel
Healthcare costs / visits	$	756,555,575					NielsenHealth Ailment Panel
Savings out of pocket costs							
OTC vs. Rx treatment costs		Cost		Savings		Annual	Source
Hearburn_OTC	$	6.98	$	13.38	$	160.56	NielsenHealth Homescan
Heartburn_Rx	$	20.36					WoltersKluwer SourceLx
Savings for consumer							
Healthcare costs (Physician visits)	$	13.75					
Medication costs (OTC vs. Rx)	$	160.56					
Total consumer savings	$	174.31					

Conclusions

The objective of this study was to outline and quantify the benefits of OTC heartburn therapy for consumers and the healthcare system in the context of treatment satisfaction and cost savings respectively. The conclusion is that consumers are highly satisfied with their OTC therapy treatment and there is direct cost savings for the healthcare system and consumers. The research also concludes there are additional opportunities for further research to quantify additional savings benefits, increasing education, expanded indication and diagnosis, and future OTC market trends.

Future research recommendations

The research recommends further research to further quantify savings benefits, OTC market trends, and consumer education:

Savings – The research documented medication and office visit savings to the healthcare system and consumers, however, further research to determine additional benefits is recommended. Recommendations include but are not limited to (a) quantifying the long term savings to health outcomes to OTC therapy against long term medical diseases and (b) expanding the cost savings inputs to loss of work, and misdiagnosis (i.e. heartburn presented as chest pain).

OTC Market Trends – Understand the future market growth in a variety of key categories is recommended. The heartburn research shows how a~15-year trend has evolved through new medication technology, identification and diagnosis, and future trends and opportunities. Further research is recommended to understand the key drivers of OTC therapy selection and the consumer choices around these decisions. Historically, it can be quantified as to what influencers have caused the drivers including but not limited to (a) the future prospective view of the market if more generic prescription products are available and (b) the increased cost of OTC therapy to the consumer.

Education – The research documents 61% of consumers are treating without a discussion with their healthcare provider; this could potentially pose future risks and opportunities. Education is recommended for consumers to understand symptoms, self diagnosis, treatment, what is severe, and when to speak with a healthcare provider.

Acknowledgements

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Footnotes

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The Consumer Healthcare Products Association (CHPA), founded in 1881, is a member-based association representing the leading manufacturers and distributors of nonprescription, over-the-counter (OTC) medicines and nutritional supplements. Many CHPA member products provide millions of Americans with safe, effective, and convenient therapies for the treatment and prevention of many common ailments and diseases.

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References

[1] NielsenHealth, The Nielsen Company, Wilton, CT
[2] "GERD". Mayo Clinic Staff. MayoClinic.com. Mayo Foundation for Medical Education and Research. May 2007.
[3] Lagergren, J. "Symptomatic GERD as a risk factor for Esophageal Adenocarcinoma". New England Journal of Medicine. March 1999.
[4] Sharma, P.; Jankowski, J. "Approaches to Barrett's esophagus treatment and the role of proton pump inhibitors and other interventions. Dichotomies and Directions in Acid-Related Disorders." Alimentary Pharmacology & Therapeutics, Supplement. 19 Supplement 1:54-59, February 2004.
[5] NielsenHealth Heartburn Ailment Panel
[6] "Smoking and Your Digestive System". The National Digestive Diseases Information Clearinghouse (NDDIC), National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, February 2006
[7] NDA submission to Office of Nonprescription Products, Food and Drug Administration by Schering and Novartis, 2008 press releases.
[8] Average healthcare cost for a office visit. US Health & Human Services, 2006; American Medical Association, 2001