Evaluation of risk versus benefit information in direct-to-consumer (DTC) television advertisements quantified by time and serious adverse effects

Chris Wang, Pharm.D., Shivani Gandhi, Pharm.D., Michael Toscani, Pharm.D., Joseph Barone, Pharm.D. FCCP, Germin Fahim, Pharm.D. BCPS

Rutgers Institute for Pharmaceutical Industry Fellowships; Ernest Mario School of Pharmacy; Rutgers, The State University of New Jersey

Background

The FDA's Presenting Risk Information in Prescription Drug and Medical Device Promotion draft guidance from May 2009 states that the time of risk versus benefit is a factor taken into consideration when evaluating audio and video DTC broadcasts. To this date, no studies have been conducted to evaluate the temporal aspect of television advertisements and its correlation to the proportion of risk versus benefit narration. Additionally, limited research is available on correlation of serious adverse effects (SAEs) and warnings communicated in television advertisements against package inserts for individual drug products.

Objective

The purpose of the study was 1) to calculate the risk-benefit duration in these advertisements and compare findings across therapeutic areas 2) to correlate risk narration in television advertisements versus SAEs and warnings listed in package inserts.

Methods

The study reviews prescription drug TV advertisements from pharmaceutical companies between the years 2010 – 2015. In this study, 18 prescription products are separated by therapeutic areas and include: disease-modifying antirheumatic drugs (DMARDs), anti-virals, respiratory agents, mood stabilizers, new oral anticoagulants (NOACs), fibromyalgia therapies, Type II Diabetes (T2D) therapies and erectile dysfunction (ED) therapies. Television advertisements for each product were viewed individually and indicators to assess risk versus benefit were collected as follows for each product:

- total communicated benefit time (in seconds)
- total communicated risk time (in seconds)
- total advertisement time (in seconds)
- percentage proportion of risk information communicated
- percentage proportion of benefit information communicated
- communication of black box warning for applicable drugs
- number of SAEs and warnings communicated in advertisement compared to number of SAEs and warnings listed in the package insert

A comparative analysis was performed using the above indicators. The outcomes that are established include (i) proportion of risk to benefit narration as a percentage across therapeutic areas (ii) correlation between SAEs narrated in advertisements and SAEs listed in package inserts. To establish a proportion of risk versus benefit narration, the percentages recorded from individual advertisements were rounded to the nearest whole number. Analysis of SAEs consisted of Black Box Warnings being communicated or not communicated in the advertisement for applicable drugs and percentage of serious warnings and precautions communicated in the advertisement that overlapped with warnings and precautions from the package insert. A range of 0-100% in increments of 20 was established to bucket number of drugs communicating the percentage of serious warnings.

Results

An analysis of risk versus benefit showed that there was a vast range of percentage differences in risk versus benefit narration across the products that were selected for this study. Figure 1 is a graphical representation of the percentages (%) of risk and benefit timing for different prescription drug products in television advertisements. Results show that there is variable consistency between drug products in the same therapeutic area.

Figure 1. Percentage of risk versus benefit narration in television advertisements

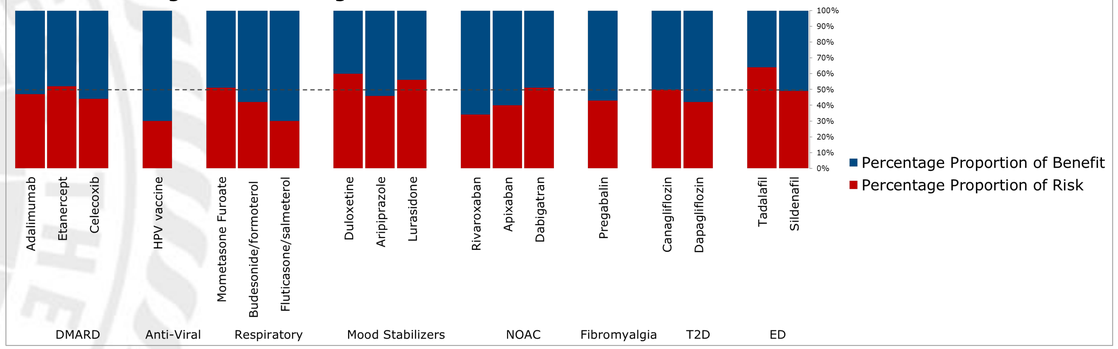


Table 1: Trends in risk to benefit narration in television advertisements by prescription drug product

Prescription Product	Risk to Benefit Narration Range
Etanercept, fluticasone/salmeterol, rivaroxaban, HPV vaccine	30:70
Adalimumab, celecoxib, budesonide/formeterol, apixaban, pregabalin, dapagliflozin	40:60
Mometasone furoate, aripiprazole, dabigatran, canagliflozin, sildenafil	50:50
Duloxetine, lurasidone	60:40
Tadalafil	70:30

Table 1 identifies basic trends in the risk to benefit proportions in television commercials. Majority of the prescription products have a 40 to 60 ratio of risk versus benefit narration. We also see that while HPV vaccine and fluticasone/salmeterol are medications with minimal risk narration; tadalafil, duloxetine and lurasidone have a higher percentage of risk illustrated in commercials.

Figure 2. Black Box Warning (n=10)

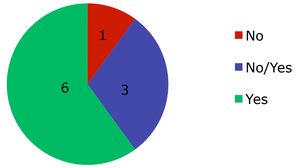
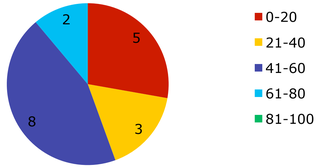


Figure 3. Serious Warnings Percentage Range (n=18)



Results (continued)

Figure 2: Out of the 10 prescription products evaluated where a black box warning was applicable according to the package insert; six products communicated this warning in their television advertisement, the three NOACs partially communicated this warning, and one product completely failed to do so. The black box warning for NOACs include two warnings and the advertisements evaluated for this study only communicated one out of the two warnings.

Figure 3: Out of the 18 prescription products evaluated for percentage of serious warnings overlapping with package insert information; five products communicated 0-20% of warnings, three products communicated 21-40%, eight products communicated 41-60%, two products communicated 61-80%, and no products communicated 81-100% of the warnings.

Limitations

- The study only uses the most recent television advertisement located online at the time of data collection. However, this may not correlate to the latest commercials broadcasted on television.
- Package inserts were pulled from the most up to date sources (manufacturer website) and may not accurately correlate with date of originally aired advertisement
- Some drug products aired multiple advertisements for the same product and communicated inconsistent information making it difficult to interpret risk versus benefit information comprehensively.

Conclusions

- These outcomes were collected to reflect the “fair balance” rule in television advertisements and if the risk narration correlated with the SAEs listed in the package inserts of each product.
- Lack of consistency exists between risk versus benefit proportions between different drug products within the same therapeutic area which may lead to commercial advantages for one product over another and misinformed patients.
- The communication of black box warnings currently differs between various therapeutic areas.
- Manufacturers must strive to incorporate a higher percentage of serious warnings into television advertisements.
- Further research is needed in this area to fully understand how consumer perception can be affected by the risk vs. benefit balance in advertisements

Author Contact Information

Chris Wang: chris.wang3@bayer.com
Shivani Ganhdi: shivani.gandhi@bayer.com

Disclosure

The authors have nothing to disclose.