Impact of adverse news media on prescriptions for osteoporosis: effect on fractures and mortality

Philip N Sambrook, Jiang S Chen, Judy M Simpson and Lyn M March

ABSTRACT

Objective: To examine the impact of a national current affairs television program about the association between osteonecrosis of the jaw and bisphosphonates on subsequent prescription use, fractures and deaths.

Design and setting: National Pharmaceutical Benefits Scheme prescription data for 9 months after the television program were used to estimate the impact of reduced bisphosphonate use on fractures and mortality.

Main outcome measures: Prescription rates, fractures and deaths.

Results: The estimated reduction of 29 633 in the number of bisphosphonate prescriptions may have resulted in 70 hip fractures, 60 other fractures and 14 deaths that would otherwise have been prevented over the 9-month period of the study.

Conclusion: Although it is important for patients to be informed of the risks of medication, media coverage that does not present a balanced view has the potential to do more harm than good.

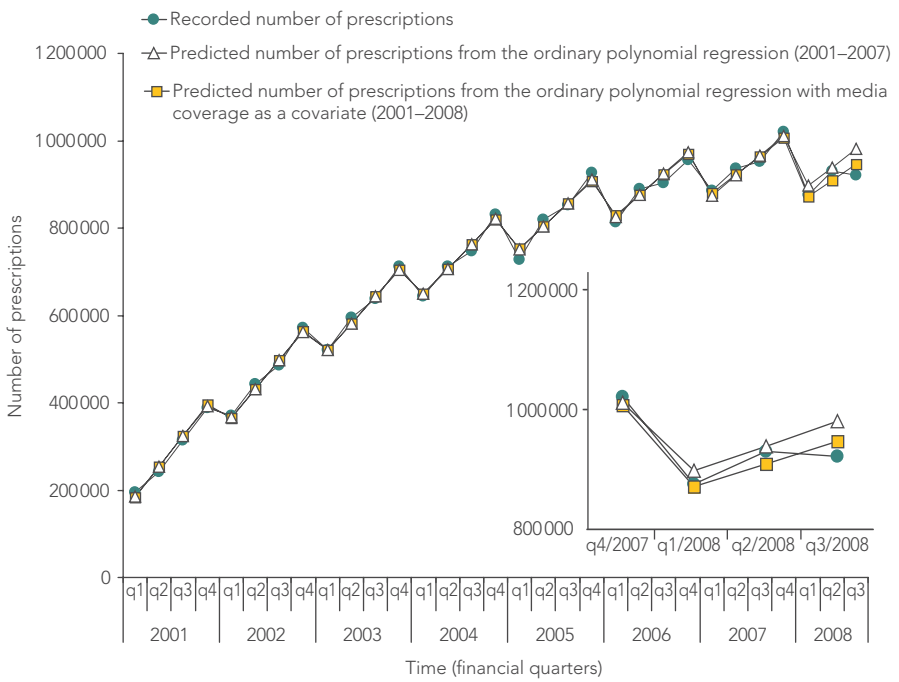
MJA 2010; 193: 154–156

The media play an increasingly important role in disseminating medical information to the general public, predominantly via television and newspapers. While it is important to disseminate knowledge to the public, the media often seem to be more intent on increasing their audience and ratings by issuing alarmist reports than informing the public of new scientific data. For example, in Canada, a public health advisory statement about the use of antidepressants in pregnancy, with subsequent coverage in the media, was widely misunderstood and led to pregnant women making decisions that may not have been in the best interests of their health and their child's health.[1] Similarly, media coverage of the findings of the Women's Health Initiative[2] have had a major effect on patient perceptions about the use of hormone replacement therapy[3] and dietary modification[4] that were not necessarily evidence-based.

In December 2007, the public broadcaster, the Australian Broadcasting Corporation (ABC), screened an item on its news and current affairs program, *The 7.30 Report*, about the association between osteonecrosis of the jaw and bisphosphonate use. The program received wide coverage in other media, including newspapers and the internet. A number of factual errors in the program were the subject of a complaint to the ABC, and these errors were subsequently acknowledged in writing by the broadcaster.[5] However, the immediate effect of the media coverage was likely to have been considerable misunderstanding among the public, as the program failed to clearly identify the different uses of bisphosphonates in the oncology and osteoporosis settings or the different absolute risks of osteonecrosis in the individual patient.

After the television program aired, there was a reduction in the number of prescriptions filled for bisphosphonates, according to statistics provided by the Drug Utilisation Sub-Committee (DUSC) of the Pharmaceutical Benefits Advisory Committee of the Department of Health and Ageing (Box 1). The graph shows that the increase in antiresorptive drug use over the period 2001–2008 was not linear. The number of Pharmaceutical Benefits Scheme (PBS) and Repatriation Pharmaceutical Benefits Scheme (RPBS) scripts usually declines in the first quarter of each year (due to PBS Safety Net provisions, which subsidise all prescription costs after patients' costs exceed a specific threshold in a calendar year) and then increases steadily over the remaining three quarters, but the pattern was different in 2008. Before 2008, the number of RPBS scripts in each quarter was always larger than the number in the corresponding quarter in the previous year. It

1 Predicted number of prescriptions compared with recorded number of prescriptions for bisphosphonates in Australia, 2001 to 2008



The predicted model fits observed scripts closely until the first three quarters of 2008 (these three quarters are also shown in expanded view). ◆

can also be seen that the decline in the number of scripts in the first quarter of 2008 was greater than in the first quarter of previous years and that the growth after the first quarter of 2008 was slower than that in previous years.

We modelled the effect of this decrease in bisphosphonate prescriptions to estimate the impact on fractures and associated mortality in the Australian population.

METHODS

The DUSC provided quarterly numbers of RPBS scripts filled for antiresorptive drugs for the period 2001–2008, as well as information on bone densitometry services (item numbers 12306, 12309, 12321 and 12323) for the years 2006–2008. These statistics included only claims processed by Medicare Australia, not services provided to public patients in hospital.

We developed two polynomial regression models of the quarterly number of RPBS scripts. Both included continuous covariates for year (Year 1 to Year 7 or 8) and quarter (Quarter 1 to 4), and we tested squared terms in year and quarter, as well as all two-way interaction terms.

For Model 1, we used the data for 2001–2007 and then used this model to predict the number of scripts in the first three quarters of 2008. The average difference between the predicted numbers based on the prior 7 years and the recorded numbers for the first three quarters of 2008 was considered as the effect size of the media coverage.

For Model 2, we used data for the whole period of 2001–2008 and included an extra covariate (0 before the broadcast and 1 after the broadcast) for the effect of the media coverage on the use of antiresorptive drugs.

To be conservative, we selected the model that gave the smaller estimate of the effect of the media coverage. Because each patient usually has three scripts per quarter, we estimated the number of people affected by the media coverage by dividing the selected value by three.

The age and sex distribution of those not obtaining bisphosphonates after the media coverage was assumed to be the same as that for patients taking antiresorptive drugs between April 2007 and March 2008. We estimated fracture incidence rates for osteoporotic fractures and hip fractures by age and sex using the fracture risk calculator developed by the Garvan Institute in Sydney.[6] The number of hip fractures and total fractures expected in each group was estimated by multiplying the incidence rate by the number of people in the group. To calculate the number of fractures that may have resulted from the adverse media coverage, we assumed, based on previous studies,[7-9] that bisphosphonates produce a 40% reduction in hip fractures and a 25% reduction in other fractures. In order to estimate the additional number of deaths, we further assumed that 20% of people who had a hip fracture would die within the first 6 months after the fracture.[10]

RESULTS

The results from the two regression models are presented in Box 2. The estimated reduction in the number of prescriptions using Model 1 was 29 633, compared with 31 697 using Model 2. Based on the value of 29 633, the number of men and women affected by the media coverage was estimated to be 9878, representing 3.1% of the average number of people (316 304) receiving antiresorptive treatment in 2007. It is worth noting that this effect persisted to the end of the study (ie, the September quarter of 2008) (Box 1).

The number of hip fractures and total fractures expected in each age–sex group and the estimated number of fractures and deaths that were not prevented as a result of the media coverage are shown in Box 3. In total, 415 osteoporotic fractures, including 174 hip fractures, were expected to occur each year among these 9878 men and women. We estimated that 70 hip fractures, 60 other fractures and 14 deaths would have been prevented if the 9878 people affected by the media coverage had taken antiresorptive drug treatment (Box 3).

DISCUSSION

Our findings suggest that a television program and ensuing media coverage highlighting the association between bisphosphonate use and an uncommon adverse event, osteonecrosis of the jaw, potentially resulted in 130 fractures and 14 deaths that may otherwise have been prevented.

Although it is important for patients to be informed of the risks of medication, unbalanced media coverage has the potential to do more harm than good.[1,4] Indeed, it has recently been reported that the predicted rising trend in hip fractures in Australian women has been reversed, coincident with increased prescribing of bisphosphonates.[11] When antiresorptive drugs are used to treat osteoporosis, the very small risk of jaw osteonecrosis must be kept in perspective and balanced against their demonstrated benefit in reducing fractures and death.

The incidence of osteonecrosis of the jaw after oral bisphosphonate treatment for osteoporosis has been estimated to be between 1 in 10 000 and 1 in 100 000 patient treatment-years,[12] although a retrospective postal survey in Australia provided higher estimates of risk.[13] In cancer patients, for whom bisphosphonates are primarily used as high-dose adjunctive therapy to reduce the number of skeletal-related events or to treat hypercalcaemia, the reported incidence may be as high as 1 in 1000, increasing to 1 in 10 after tooth extraction.[12]

2 Regression models for the number of PBS and RPBS prescriptions for bisphosphonates, 2001–2008

	Model 1 (2001–2007)		Model 2 (2001–2008)	
Variable	Coefficient (95% CI)	*P*	Coefficient (95% CI)	*P*
Media impact*	−29 633		−31 697 (−61 502 to −1893)	0.04
Year	224 318 (210 471 to 238 165)	< 0.001	226 383 (211 665 to 241 101)	< 0.001
Year^2	−13 188 (−14 717 to −11 659)	< 0.001	−13 188 (−14 840 to −11 535)	< 0.001
Quarter	72 994 (62 400 to 83 589)	< 0.001	75 472 (64 491 to 86 453)	< 0.001
Year × quarter	−3930 (−6299 to −1561)	0.002	−4757 (−7078 to −2435)	< 0.001
Constant	−94 632 (−128 962 to −60 302)	< 0.001	−100 826 (−137 028 to −64 623)	< 0.001

PBS = Pharmaceutical Benefits Scheme. RPBS = Repatriation Pharmaceutical Benefits Scheme. * The reduction in the number of scripts by media impact was divided by three to obtain the number of people affected, assuming that each patient usually has three scripts per quarter. ◆

3 Estimated number of people not receiving bisphosphonates after media coverage, and estimated excess hip fractures and other fractures resulting from treatment avoidance, by age and sex

Age group (years)	People not treated	Hip fracture rate/year*	Expected hip fractures/year†	Total fracture rate/year*	Expected total fractures/year†
Women					
< 70	2329	0.007	15.65	0.024	56.45
70–74	1272	0.015	18.46	0.037	47.36
75–79	1532	0.018	28.27	0.043	65.78
80–84	1519	0.023	35.62	0.049	75.05
85–89	998	0.030	29.55	0.057	56.45
⩾ 90	488	0.033	16.18	0.060	29.51
Men					
< 70	636	0.003	1.68	0.014	8.93
70–74	276	0.011	3.12	0.039	10.84
75–79	353	0.019	6.66	0.057	20.30
80–84	294	0.031	9.10	0.082	24.01
85–89	141	0.050	6.98	0.111	15.67
⩾ 90	40	0.062	2.48	0.127	5.07
Total	*9878*		*174*		*415*

Estimated excess fractures and deaths in the year following Australian Broadcasting Corporation media coverage: 70 hip fractures,‡ 60 other fractures§ and 14 deaths.¶

* Estimated using Garvan Institute fracture risk calculator.[6] † Expected fractures per year do not correspond exactly to (number treated × fracture rate/year) because fracture rates are rounded figures. ‡ Assuming that antiresorptive drug treatment reduces hip fractures by 40% — ie, 174 × 0.4 = 69.6. § Assuming that antiresorptive drug treatment reduces other fractures by 25% — ie, (415 – 174) × 0.25 = 60.3. ¶ Assuming a 20% death rate in the first 6 months after hip fracture — ie, 70 × 0.20 = 14.0). ◆

Other factors may have affected the use of antiresorptive drugs in 2008. For example, in some patients, bisphosphonate therapy may be stopped after 5 years of the treatment if bone density readings are stable. However, this is not a likely explanation for the usage pattern observed, as the number of people undergoing bone density testing in 2008 was in fact lower than in previous years (according to data provided by the DUSC). Some physicians may also have followed guidelines suggesting that selected patients be referred to a dentist before starting bisphosphonate treatment. However, these guidelines should have affected the use of bisphosphonates throughout the period since their introduction in 2006.[14] Thus, any effects should have been part of the growth trend from 2001 to 2007, which would have been included in the regression models. We used an average but conservative effect size for the reduction in fractures with different bisphosphonates. Although we modelled prescription usage after the television story aired, other sources of medical information, such as the internet, may also have contributed to patient perceptions about bisphosphonate use.

Responsible reporting of health data to the public is a challenge. Great skill is needed to strike the right balance between alerting but not alarming. Reporters and the general public alike have poor understanding of epidemiological principles and application of the risk to individuals. It behoves the medical community to conduct appropriate studies to gain unbiased assessment of risks, and it behoves media personnel to be more responsible in their reporting so that such alerts first do no harm.

COMPETING INTERESTS

Philip Sambrook serves on the medical advisory boards of and has received speaker fees from Amgen, Merck Sharp & Dohme, Novartis, Sanofi-Aventis and Servier.

AUTHOR DETAILS

Philip N Sambrook, MD, LLB, FRACP, Rheumatologist[1]
Jiang S Chen, PhD, Postdoctoral Fellow[2]
Judy M Simpson, BSc, PhD, Biostatistician[3]
Lyn M March, PhD, FRACP, Rheumatologist[1]
1 Royal North Shore Hospital, Sydney, NSW.
2 Institute of Bone and Joint Research, University of Sydney, Sydney, NSW.
3 Sydney School of Public Health, University of Sydney, Sydney, NSW.
Correspondence:
sambrook@med.usyd.edu.au

REFERENCES

1 Einarson A, Schachtschneider AK, Halil R, et al. SSRI's and other antidepressant use during pregnancy and potential neonatal adverse effects: impact of a public health advisory and subsequent reports in the news media. *BMC Pregnancy Childbirth* 2005; 5: 11.
2 Rossouw JE, Anderson GL, Prentice RL, et al; Writing Group for the Women's Health Initiative Investigators. Risks and benefits of estrogen plus progestin in healthy postmenopausal women: principal results from the Women's Health Initiative randomized controlled trial. *JAMA* 2002; 288: 321-333.
3 McIntosh J, Blalock SJ. Effects of media coverage of Women's Health Initiative study on attitudes and behavior of women receiving hormone replacement therapy. *Am J Health Syst Pharm* 2005; 62: 69-74.
4 Yngve A, Hambraeus L, Lissner L, et al. The Women's Health Initiative. What is on trial: nutrition and chronic disease? Or misinterpreted science, media havoc and the sound of silence from peers? *Public Health Nutr* 2006; 9: 269-272.
5 Sambrook P. President's report. *Aust N Z Bone Miner Soc Newsletter* 2008; Issue 8: 1. http://www.anzbms.org.au/news/newsletters/ANZBMSnews_Apr08.pdf (accessed Sep 2008).
6 Garvan Institute. Fracture risk calculator. http://www.garvan.org.au/promotions/bone-fracture-risk (accessed Sep 2008).
7 Wells GA, Cranney A, Peterson J, et al. Alendronate for the primary and secondary prevention of osteoporotic fractures in postmenopausal women. *Cochrane Database Syst Rev* 2008; (1): CD001155.
8 Wells GA, Cranney A, Peterson J, et al. Risedronate for the primary and secondary prevention of osteoporotic fractures in postmenopausal women. *Cochrane Database Syst Rev* 2008; (1): CD004523.
9 Black DM, Delmas PD, Eastell R, et al. Once-yearly zoledronic acid for treatment of postmenopausal osteoporosis. *N Engl J Med* 2007; 356: 1809-1822.
10 Center J, Nguyen T, Schneider D, et al. Mortality after all major types of osteoporotic fracture in men and women: an observational study. *Lancet* 1999; 353: 878-882.
11 Fisher AA, O'Brien ED, Davis MW. Trends in hip fracture epidemiology in Australia: possible impact of bisphosphonates and hormone replacement therapy. *Bone* 2009; 45: 246-253.
12 Khosla S, Burr D, Cauley J, et al. Bisphosphonate-associated osteonecrosis of the jaw: report of a task force of the American Society for Bone and Mineral Research. *J Bone Miner Res* 2007; 22: 1479-1491.
13 Mavrokokki T, Cheng A, Stein B, Goss A. Nature and frequency of bisphosphonate-associated osteonecrosis of the jaws in Australia. *J Oral Maxillofac Surg* 2007; 65: 415-423.
14 Sambrook PN, Olver I, Goss A. Bisphosphonates and osteonecrosis of the jaw. *Aust Fam Physician* 2006; 35: 801-803.

(Received 19 Oct 2009, accepted 18 Feb 2010) ❑