

## Making medical news and accountability

*Prepublication press coverage "may be enough to do you serious harm"*

AT THE END OF MAY THIS YEAR the Rheumatology Associations of Australia and New Zealand hosted a combined scientific conference in Christchurch, New Zealand. Notable among the presentations was a retrospective observational study on the association between gastrointestinal (GIT) bleeding and the use of aspirin, non-steroidal anti-inflammatory drugs (NSAIDs), or cyclo-oxygenase II (COX-II) inhibitors (Box 1). The essential finding of the study was that among 20 patients with bleeding related to peptic ulcer or oesophagitis, six were taking low-dose aspirin, four were taking COX-II inhibitors and one an NSAID. The researchers concluded "that aspirin is still more commonly associated with GIT bleeding than conventional NSAIDs and COX-II inhibitors".

One week later, the headline "Doctors warn: just one tablet of aspirin a day may be enough to do you serious harm" appeared on page one of the respected morning broadsheet the *Sydney Morning Herald*. The accompanying story, reprinted in Box 2, related that a "world first study" from the Prince of Wales Hospital in Sydney "found that: where any drug was implicated in [GIT] haemorrhage, low-dose aspirin was consistently the likeliest culprit — ahead of anti-inflammatory drugs which are more often blamed for the condition. All 120 patients eventually recovered but many had to have transfusions, adrenaline shots or surgery." The chairman of rheumatology at the Prince of Wales Hospital was quoted as saying that "It is of some considerable concern that aspirin, even at 100 mg a day, is likely to be associated with gastrointestinal hemorrhage", adding, "When patients are admitted vomiting and passing blood, it's pretty dramatic".

Such a blood, guts and fear story proved irresistible to the media. Before the day was out television news and radio commentators carried the story with such graphic gusto as "new research shows that even small doses of aspirin can cause potentially fatal stomach bleeding", or "a daily dose of aspirin to thin the blood to avoid heart disease or stroke may be deadly, causing ulcer bleeding". On the day, the story was carried by at least 20 media outlets, including most of the prime-time television evening news broadcasts in eastern Australia (information gathered by Media Monitors Australia). The process of transferring information from the researchers to the newspaper had transformed a conference poster of a retrospective observational study of only 20 patients into sensational medical news!

This breaking of "a world first study" undoubtedly caused disquiet and despair in the community, as people with heart or cerebrovascular disease were faced with the decision as to whether they should continue taking aspirin to prevent a heart attack or stroke, or stop taking it to prevent a "fatal" stomach bleed. This is an impossible choice in the absence of vital information, such as the absolute risk of GIT bleeding and the benefit-to-harm ratio for low-dose aspirin. Their doctors were also impotent, as they were not privy to information on which the news story was based.

### **1: The impact of cyclo-oxygenase II (COX-II) inhibitors on gastrointestinal (GIT) bleeding**

**Background:** Our previous study demonstrated that aspirin is a more commonly associated risk factor for GIT bleeding than both conventional NSAIDs and COX-II inhibitors. This study reports the impact of COX-II inhibitors on GIT bleeding in a third time period (2001) following the listing of a second COX-II inhibitor (rofecoxib).

**Method:** Medical records of patients admitted to Prince of Wales Hospital, Sydney, with GIT bleeding or those requiring a gastroscopy during the period of 1 March to 31 August 2001 were reviewed.

**Results:** 31 out of 321 patients have met the criteria. Of these 20 had bleeding related to peptic ulcer disease or reflux oesophagitis. Of this group, four were on a COX-II inhibitor, six were taking low dose aspirin (100–150 mg/d) and one was on a conventional NSAID. One patient was on clopidogrel only and another on warfarin only. Two patients were on prednisolone. Only two patients had a previous history of peptic ulcer disease. Overall in both studies of the three time periods, 35% were on aspirin, 20% on NSAID's and 11% were on COX-II inhibitors. A very small percentage were on warfarin, clopidogrel or prednisolone, and the remainder were not on any medications known to be associated with increased risk of GIT bleeding.

**Conclusion:** Our most recent data confirms our previous study that aspirin is still more commonly associated with GIT bleeding than conventional NSAID's and COX-II inhibitors.

J Bertouch, L Lee, H P McNeill, T Bolin  
Prince of Wales Hospital, Australia

Because of the implications of such a sensational story, the Journal sought to put the report into context, approaching both a cardiologist and the story's creators for comment (see the letters following this article). In response to this request, the medical researchers raised the philosophical question of when a scientific *fact* becomes established and accepted as *fact*, and whether this process requires the blessing of peer review. The journalists stressed their responsibility to report medical matters and pointed out that journalistic judgement takes precedence over scientific or evidential rigour. It should be no surprise that the research on which this *medical news* was based has yet to appear in the scientific literature.

Does this matter?

The timing of wide dissemination of medical research outcomes to other researchers, clinicians and the public remains a contentious issue.<sup>1-4</sup> Journalists want to be the first to break important medical news, and their editors know that there is an insatiable public appetite for health matters, more so if dressed up as "miraculous cures" or "dire threats".<sup>5</sup> Researchers also want to be first in reporting new findings, as this is critical for their research funding, professional advancement and peer approval. Most do this through respected peer-reviewed journals. Despite these similar aspirations, there exists an inherent tension between the two cultures: "Media constraints of time, brevity and simplicity preclude careful documentation, nuance positions and precautionary qualifications that scientists feel are necessary to present their work."<sup>2</sup> And at the centre of this tension is what the participants perceive science to be.

**2: Doctors warn: just one tablet of aspirin a day may be enough to do you serious harm**

Even very low doses of aspirin designed to prevent stroke and heart attack can cause life-threatening stomach bleeding, says a Sydney study that challenges the widespread use of the blood-thinning therapy.

The world-first study looked at all patients admitted to Prince of Wales Hospital with gastrointestinal bleeding during three six-month periods between 1999 and 2001. It found that where any drug was implicated, low-dose aspirin was consistently the likeliest culprit — ahead of anti-inflammatory drugs, which are more often blamed for the condition.

All 120 patients eventually recovered, but many had to have transfusions, adrenaline shots or surgery to stem the bleeding.

The hospital's chairman of rheumatology, Jim Bertouch, said the results indicated the preventive aspirin doses most commonly used in Australia — a single daily tablet of 100–150 milligrams — may be too high. He suggested that doses of 75 mg, already used in Britain, might be more appropriate.

Low-dose aspirin was implicated in up to a third of the gut hemorrhages diagnosed during the study, Dr Bertouch said.

By contrast, arthritis medications, previously maligned as likely to cause stomach bleeding, caused fewer bleeds, about a quarter of the total.

But the new COX-2 inhibitor arthritis drugs, which include the popular Celebrex — heavily promoted as safer for the stomach than older anti-inflammatories — were still involved in one in eight hemorrhages.

The rest of the bleeds were either not linked with any drugs, or with a range of other drugs.

"It is of some considerable concern that aspirin, even at 100 mg a day, is likely to be associated with gastrointestinal hemorrhage", said Dr Bertouch, who presented the research at a rheumatology conference in New Zealand last month. "When patients are admitted vomiting and passing blood, it's pretty dramatic".

Terry Bolin, chairman of the Prince of Wales Hospital's Gastrointestinal and Liver Unit and a co-author of the study, said "We've known for years that aspirin was a risk but we were unaware that the really low dose aspirin had the same risk."

Doctors should check whether patients were carriers of *H. pylori* bacteria that precede stomach ulcers, because this further increased bleeding risk from aspirin and other drugs, Associate Professor Bolin said.

Associate Professor Con Aroney, a spokesman for the National Heart Foundation, said the benefits of aspirin outweighed the risks for people with a history of coronary heart disease or stroke. But daily aspirin was not recommended to prevent heart disease in healthy people.

Julie Robotham

Medical Writer, *Sydney Morning Herald* (June 7, 2002: 1)

conveys a sense that the information is valued, accurate and widely accepted.

But the softness of prepublication information is highlighted by the fact that almost half of the abstracts of scientific or clinical meetings are not published,<sup>7</sup> and a quarter of meeting abstracts that receive prominent press coverage share the same fate.<sup>8</sup>

One feature of medical reporting is sensationalism.<sup>5,9-11</sup> This phenomenon has been attributed to "miscommunication" arising from the different cultures and styles of science and journalism.<sup>10</sup> However, at times both parties may benefit from sensational stories.<sup>11</sup> The reporter has a front-page story, and the researchers (and their institutions) bask in the publicity. But, more importantly, sensationalism may occur because no one is responsible or accountable "for the results of transactions between reporters and researchers in the way that an editor is responsible for the peer review process and content of a scientific journal . . . In the wake of a sensationalised medical story, the involved parties can always point the finger at each other".<sup>11</sup> This lack of accountability has prompted a call for a watchdog to spotlight both good and bad medical stories.<sup>11</sup>

Robotham and Whitehead stress that "a basic tenet of journalistic ethics is that journalists should be independent" (see the letters following this article). But with independence comes responsibility and accountability, and this applies on both sides of the fence: both to reporters and researchers and their respective institutions. In the absence of such accountability the public will continue to be bombarded by the touting of "miracle cures" — which, on closer inspection, are years away or apply only to rats; or the proclaiming of "dire threats" to health, which, on closer scrutiny, are tentative at best and are usually followed by a dissenting story and the inevitable backflip.

Subjecting the public to a roller coaster ride of excitement and disappointment or anxiety and anger will eventually engender cynicism for medical research and its reporting, and this would be a shame. After all, the aim of both parties is to publish and report medical science for the good of all.

**Martin B Van Der Weyden**

Editor, *The Medical Journal of Australia*

**See also pages 374 and 375.**

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