

# Informed consent and its documentation: Implications for medical malpractice liability

A quality assurance review at two teaching hospitals in British Columbia found that most gastroenterologists did not adequately document their discussions with patients about the possible side effects of corticosteroid use for inflammatory bowel disease.

## ABSTRACT:

**Background:** Corticosteroids are commonly used in various medical specialties and are associated with side effects that can affect every body system. While this is a concern for all physicians, it is of particular concern for gastroenterologists, who typically prescribe high doses of steroids over long periods when treating patients with inflammatory bowel disease. Some patients in Canada treated with steroids have brought lawsuits against physicians, claiming they were not adequately informed of these side effects or the alternative therapies available. The key factor in most cases where the court agreed with the patient was the physician's failure to provide thorough documentation demonstrating that the patient was adequately informed of the possible side effects of therapy.

**Methods:** A retrospective chart review was conducted at two teaching hospitals in Vancouver, British Co-

lumbia, from 1 September to 31 October 2010. The review included charts of patients admitted to the gastroenterology service with the diagnosis of inflammatory bowel disease or ulcerative colitis or Crohn disease. The review excluded charts of patients who were taking steroids prior to admission.

**Results:** A total of 36 charts were reviewed. The charts indicated that 13 patients had Crohn disease and 23 patients had ulcerative colitis. After admission, 8 patients were started on oral steroids and 28 patients on intravenous steroids. Only 2 of the 36 charts contained documentation of discussion with patients about avascular necrosis and osteoporosis as possible side effects of steroid therapy. Only 1 chart documented discussion of cosmetic, psychological/emotional, and infection risks of steroid therapy.

**Conclusions:** We found inadequate documentation demonstrating discussion of side effects prior to initiation of steroid therapy in patients hospitalized for inflammatory bowel

disease. These findings and the history of successful lawsuits brought against physicians highlight the need to follow an informed consent process, to document discussions about possible side effects, and to closely monitor patients to prevent harm and avoid litigation associated with steroid use.

## Background

Corticosteroids are commonly prescribed by physicians in various medical specialties for a number of disorders. Gastroenterologists typically use relatively high doses and for lon-

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ger periods, and often prescribe multiple courses. The most common indication for use is inflammatory bowel disease (IBD). Because patients with IBD tend to be young when therapy begins, they use steroids for a longer time and their chances of developing side effects are high. The adverse effects of corticosteroids are well known and can be disabling. Among the most serious of complications and the complication most commonly resulting in medical malpractice suits is avascular necrosis (AVN).

Although avascular necrosis of the hips has been reported to occur in patients with inflammatory bowel disease who are not taking corticosteroids,<sup>1,2</sup> the association of avascular necrosis and corticosteroid use is well documented. There appears to be a dose-related effect, with higher daily doses associated with increased chance of an adverse event.<sup>3</sup> In fact, a significant reduction in bone density can occur in the first few weeks of steroid therapy. The risk of avascular necrosis of the hip is reported to be up to 4% within 6 months of steroid use, and correlates with the initial dose of steroid, not the cumulative dose.<sup>3-5</sup> Future fracture risk also correlates with daily initial dose better than with lifetime cumulative dose.<sup>6</sup>

Another significant side effect of steroids is an increased risk of infections, including opportunistic infections, especially when steroids are used in combination with other immunosuppressant agents.<sup>7</sup> Concomitant use of steroids with other immunosuppressant agents is also associated with increased mortality.<sup>7</sup> Other important concerns include cosmetic and psychological/emotional effects, and the development of hypertension, hyperglycemia, cataracts, and glaucoma.

Given the potential for significant adverse effects and the prospect of litigation, disclosure of side effects to

patients when prescribing corticosteroids is important. Moreover, documenting that side effects have been discussed is of even greater importance. Several lawsuits have been brought against Canadian physicians by patients who claimed they were not adequately informed of side effects. A number of these lawsuits have resulted in sizable awards for damages. The key factor in most of these cases was the physician's failure to provide thorough documentation demonstrating that the patient was adequately informed of the potential side effects of therapy.

## Methods

A retrospective chart review was conducted from 1 September to 31 October 2010 at two teaching hospitals in Vancouver, BC. This quality assurance project was part of the gastroenterology fellowship program at the University of British Columbia and was completed with the review and approval of the UBC Gastroenterology Training Committee. We included charts of patients admitted to the gastroenterology service with the diagnosis of inflammatory bowel disease or ulcerative colitis or Crohn disease. We excluded charts of patients who were using steroids prior to admission. We included charts of patients who were treated for their symptoms with intravenous steroids or a daily dose of oral prednisone of more than 40 mg. All charts were examined for documentation of discussions with patients of the potential side effects of steroid use prior to initiating therapy.

## Results

A total of 54 charts of patients admitted under the gastroenterology service at the two sites were available for review (24 charts from hospital A and 34 charts from hospital B). Of these, 14 charts from hospital A and 22 from

hospital B were included. The other 22 charts were excluded because the patients had not received corticosteroids. A total of 36 patient charts were included in the study. The charts indicated that 13 patients had Crohn disease and 23 patients had ulcerative colitis. After admission, 8 patients were started on oral steroids and 28 patients on intravenous steroids.

Only 2 out of the 36 charts reviewed (6%) contained documentation of discussions with patients about the side effects of corticosteroid therapy. In both of these charts, discussion of the risks of avascular necrosis and osteoporosis were documented. However, only a single chart documented discussion of the cosmetic, psychological/emotional, and infection risks.

## Relevant legal cases

Several patients claiming that their gastroenterologists did not adequately inform them about the potential side effects of steroid therapy have been awarded damages by Canadian courts, as described in the following cases.

*Levitt v. Carr.*<sup>8</sup> The patient who pursued this suit had a background of inflammatory bowel disease diagnosed in 1975. He had fairly severe disease requiring multiple courses of steroids as well as sulfasalazine. A diagnosis of ulcerative colitis led to total proctocolectomy and ileostomy on 30 April 1976. The diagnosis was subsequently revised to Crohn disease after the patient presented with recurrent inflammatory small bowel disease. He was again treated with a prolonged course of corticosteroids. In July 1977 the patient began to experience pain in his right hip. He was diagnosed with avascular necrosis involving his right femoral head. Because of a number of infectious complications in his right hip unrelated to AVN, replace-

ment of his joint did not occur until May 1987. In the interim, the patient developed AVN in his left femoral head and left hip replacement surgery was performed in June 1979.

Eventually, the patient sued the gastroenterologist, alleging that the “excessive” doses of steroids prescribed for prolonged periods caused him to suffer AVN. The patient also alleged that the gastroenterologist did not disclose all of the risks of steroid therapy, including the risk of AVN, or

against the gastroenterologist and in favor of the patient. The decision was based on expert opinion that there was a link between steroid use and the development of AVN. The ruling stated that all the serious side effects of steroid use should have been disclosed to the patient, especially when he was on a prolonged course of treatment and reluctant to undergo surgery. The ruling also stated that the gastroenterologist should have made a “more concerted effort” to obtain the patient’s

gastroenterologist in May 1980. She continued to have symptoms of active inflammatory disease and was prescribed several courses of oral and intravenous corticosteroids. In July 1991 she developed AVN involving both of her hips and shoulders, and subsequently had both of her hips replaced. Unfortunately, the patient’s difficulties did not end with her Crohn disease and AVN. She began to experience a variety of neurological symptoms and was diagnosed with multiple sclerosis in 1997.

In 2000 the patient sued the gastroenterologist, claiming that she was not made aware of all of the potential side effects of steroids, including AVN. The gastroenterologist testified that he did in fact have this discussion with her on a number of occasions, and explicitly warned her about the possibility of AVN. However, there was nothing in the medical records that corroborated this testimony, and the court favored the patient’s recollection of events. The patient had been previously prescribed 6-MP, but did not take this immunosuppressant medication as she found it too expensive. Several other gastroenterologists and orthopaedic surgeons testified that AVN was a known complication of steroid use, and that the dose of prednisone prescribed might have been excessive.

On the issue of informed consent, the judge believed that a reasonable person with the patient’s condition would have consented to the continued treatment with corticosteroids had she been made aware of the risk of AVN given how rare its occurrence. On the issues of negligence and causation, however, the judge ruled in favor of the patient based on finding that the gastroenterologist used excessive amounts of steroids, and that there was a clear association with its overuse and development of AVN.

### **Only 2 out of the 36 charts reviewed (6%) contained documentation of discussions with patients about the side effects of corticosteroid therapy.**

provide adequate information about alternatives to surgery until it was too late. The gastroenterologist testified that the patient had been adequately advised of the risks of steroid therapy and surgical alternatives, and his legal counsel questioned the association between steroid use and AVN.

Testimony was provided by expert witnesses, including two orthopaedic surgeons, other gastroenterologists, a rheumatologist, and a clinical pharmacologist. All witnesses connected steroid use with the development of avascular necrosis and described AVN as a rare but potential complication. The gastroenterologist was asked to submit to the court all of his records pertaining to the patient, including both clinic and hospital notes.

After reviewing all the evidence and expert testimony, the judge ruled

consent to surgery as opposed to continuing on steroids.<sup>8</sup> The gastroenterologist testified that he did have a detailed discussion with the patient about the risks of steroids, but documentation of this discussion was not found in the medical records. As a consequence, the patient was awarded pecuniary and nonpecuniary damages as well as legal costs. The total award to the patient in 1992 was approximately \$1 million.

*Rhine v. Millan.*<sup>9</sup> The patient who pursued this suit was diagnosed with Crohn disease in the late 1970s. She had fairly severe disease and underwent surgical bowel resection in March 1979. She was started on intravenous corticosteroids at that time by her original gastroenterologist. The patient then switched to another gas-

General damages would normally have been in the range of \$200 000 to \$225 000, but were reduced to \$125 000 because the patient's multiple sclerosis was considered an independent mitigating circumstance.

## Conclusions

Our findings are of great concern from a medicolegal perspective. Although the lack of documentation does not mean that the physician did not discuss potential side effects of medical therapy with the patient, there is no way to confirm the discussion occurred. Medical records are the only objective evidence that discussions with patients actually took place. In a number of Canadian cases on this issue, including the two described above, the physicians maintained that a discussion did take place, but the lack of documentation led the court to favor the patients' recollection of events.

To our knowledge, there are no clinical guidelines that recommend how much information regarding side effects of steroids needs to be disclosed and documented. This is especially important for physicians prescribing corticosteroids because of the numerous potential side effects. Our belief is that common and serious side effects should be discussed and documented with the goal of obtaining informed consent. Deciding which side effects among the many require disclosure is always a challenge. From a medicolegal perspective, we suggest that physicians disclose any material risks, regardless of how uncommon, that a reasonable person in a similar situation would want to know about.<sup>10</sup> We note that obtaining informed consent is not only a medicolegal obligation, but also an ethical obligation. Ensuring disclosure of any medication side effects and documenting the disclosure will reduce

chances of a successful patient complaint, increase patient-physician trust, and increase the likelihood of patient acceptance in the event of a significant adverse effect.

We can only speculate about the various reasons for lack of documentation: time constraints, concern that the patient will refuse the proposed therapy, and lack of awareness that documentation is needed. We believe, based on this study, that measures need to be taken to educate and remind physicians about the great importance of having discussions about side effects with their patients before embarking on therapy, and documenting that these discussions took place. This is especially important given that in a teaching hospital the physicians who discuss treatment with the patient and write the orders for treatment in the medical record may be house staff who are less aware of steroid side effect issues than the staff physicians. One possible intervention that could facilitate these discussions with inpatients and provide appropriate documentation is the use of a preprinted order set. When prescribing medications such as steroids the physician would use standardized orders that include a section to document what side effects were discussed. For outpatients, an option might be an information sheet highlighting the most common and serious side effects of a medication, which could be reviewed and signed by the patient and physician before becoming part of the medical record.

Discussion with a patient about the side effects of steroids cannot be supported in a court of law without documentation. As highlighted in the legal cases described here, lawsuits associated with steroid use are costly and rulings against physicians stem from a lack of documented informed consent. Physicians must document

discussions with patients and obtain informed consent. This should occur with every course of corticosteroid treatment as well as for every drug that is associated with significant adverse effects.

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## Competing interests

None declared.

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