Steroid-induced osteonecrosis in inflammatory bowel disease: Canadian legal status

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ABSTRACT

The challenges of treating inflammatory bowel disease (IBD) with steroids has not only serious medical implications but also the potential for legal ramifications. There are a number of possible side-effects with steroid use, including the risk of avascular necrosis, or osteonecrosis (ON).

If the clinician treats an IBD patient with steroids and is sued, the legal principles of standard of care and informed consent are triggered. These common law principles form the basis of medical negligence actions against physicians and affect physicians sued in common law jurisdiction such as Canada, United States and Commonwealth countries. Allegations of medical negligence are predicated on assumptions that physicians in prescribing steroids for IBD may have breached the standard of care in relation to dosage, both in time and amount prescribed, and in failure to refer the patient for surgery in a timely fashion. Lack of informed consent is almost always an issue.

At least 10 lawsuits in Canada relating to steroid use in IBD have occurred since 1990 and the risk of legal actions against gastroenterologists in Canada has more than doubled since the 1980s. A recent (1999) Canadian court judgement against a gastroenterologist alleging an inappropriate prescribing of steroids for IBD that resulted in ON, provided a change in the stance of the courts. Emphasis was placed on standard of care, informed-consent status, timing of referral for surgery, and analysis employed by the court resulted in a favourable finding for the defendant gastroenterologist. This case provides a contrast to earlier judgements in favour of patients. In spite of the favourable finding for the gastroenterologist the court still concluded, based on evidence of orthopaedic surgeons and gastroenterologists, that a direct link existed between steroid use in treatment of IBD and development of ON.
INTRODUCTION

Use of steroid therapy in treatment of various medical conditions is perceived to be the potential cause of a variety of side effects. Osteonecrosis (ON) [often referred to as avascular necrosis] following steroid therapy has been cited in numerous medical treatments but it is still unexplained why only a limited number of these complications occur. It has been assumed in the medical community that occurrence of ON in inflammatory bowel disease (IBD) following steroid therapy is a result of the treatment rather than the disease or some other factor. Consequently the courts have been faced with medical experts automatically making this assumption, although there appears to be limited scientific support for this statement.

There are five reported legal decisions in Canada (although other actions are brought) concerning treatment of steroids in IBD cases which purportedly caused ON. There may be limited scientific evidence regarding whether treatment of IBD with steroids does carry with it the risk of ON. Experts in the reported legal cases state as a given that a plaintiff who develops ON following treatment with steroids does so as a result of steroid therapy. In other words, there appears to be no consideration given that ON may be disease-based rather than steroid-induced. The purpose of this chapter is to demonstrate the ramifications of this premise being accepted as medical fact by the courts by examining the legal decisions, particularly in terms of standard of care and consent issues.

LEGAL PRINCIPLES

Consent

The common law is that plaintiffs must establish, on a balance of probabilities, that they were not informed of the risks of treatment and that the result would have been different had they been fully informed of the risks. The test as enunciated by the Supreme Court of Canada is an objective one. If the plaintiff is not informed of risks, the issue becomes whether a reasonable person, in the position of the plaintiff, would have declined the course of treatment if fully informed of the risks. Even if the legal test was a subjective one, the issue is would this particular plaintiff, being fully informed of the risks of treatment, accept it.

In IBD, plaintiffs would have to be advised not only of risks inherent in steroid therapy, but also the possible alternatives and risks inherent in other treatments and in no treatment. Courts have accepted that surgery is regarded in the medical profession as a last resort in treatment of Crohn’s disease.

In law a material risk is a significant risk that poses a real threat to the plaintiff’s life, health or comfort. In considering whether a risk is material one must balance the severity of the potential result and the likelihood of its occurring. A risk which is a mere possibility is not a material risk unless, even though rare in occurrence, its consequences are serious. On the other hand, if there is a significant chance of slight injury this too may be held to be material. Definition of a material risk depends on the specific facts of each case. Plaintiffs