Dr. Roger Poisson: "I have learned my lesson the hard way"

Fran Lowry

Résumé : Le Dr Roger Poisson de Montréal affirme avoir «appris sa leçon à la dure» après qu'une enquête effectuée aux États-Unis a établi qu'il n'avait pas suivi correctement les règles dans le cas de certaines patientes qu'il avait inscrites au National Surgical Adjuvant Breast and Bowel Project. Au cours de cette entrevue, le Dr Poisson soutient qu'il n'a jamais eu l'intention de nuire à l'étude. Il affirme aussi qu'on n'a pas abordé son cas sous l'angle approprié et que l'étude même n'a pas été jugée invalide à cause de ses erreurs : «Les critères d'admissibilité dont je n'ai pas tenu compte étaient évidemment de peu d'importance.»

I remember interviewing Dr. Roger Poisson in 1984, just before results of the extensive National Surgical Adjuvant Breast and Bowel Project (NSABP) trial were published and long before reports were published linking him with fraudulent data related to the project.

The results of that large and lengthy study were delivered at that year's annual meeting of the Royal College of Physicians and Surgeons of Canada. It was an unforgettable meeting for a number of reasons. For one, the pope made an appearance in Montreal at the same time, arriving in his bullet-proof, glass-walled "popemobile" at a cathedral near the Queen Elizabeth Hotel, where the meeting was being held. For another, Dr. Bernard Fisher, the coordinating author of the NSABP trial, imposed a media ban — no reporters were to cover his talk on the trial. (The trial had determined that lumpectomy plus adjuvant therapy with chemotherapy and radiation was indeed as efficacious as total mastectomy in the treatment of women with breast cancer.)

As a relatively new and still naïve reporter, I complied with the ban. Another more intrepid and experienced reporter rightly ignored the ban and covered Fisher's talk, which was, after all, being presented in a public venue.

As a result of this, I received a lecture from my editor and was told to get the story from another source. This is how I met Roger Poisson, a surgeon at Hôpital St-Luc in downtown Montreal. I have conducted many interviews with many doctors over the years and can usually remember few, if any, details about them, but I remember that interview very well. As we talked Poisson never rushed me and he took plenty of time to answer all my questions. This was notable — as a rule, surgeons are always in a hurry. But what I really remember is the compassion he showed for women with breast cancer. I remember him being very concerned that they be spared the mutilation that comes with mastectomy. Why not just remove the tumour and preserve the breast — if that was possible — and then treat with radiation and perhaps chemotherapy?

For American surgeons at that time, the Halsted radical mastectomy (or the modified radical mastectomy) was the gold standard of surgical treatment for breast cancer. As Poisson told me during a recent interview, Nancy Reagan, Happy Rockefeller and Betty Ford, all stricken with breast cancer, had their breasts completely removed. One would assume that these women had access to the best medical care that the US had to offer; in fact, total or radical mastectomy was considered the best treatment, at least in the US, even as recently as October 1987.

In Canada, the treatment for breast cancer has been a bit different, and for some time. According to Poisson, Canada has been ahead of the US in its treatment of the disease. When we spoke three months ago, in June, he maintained that the rules he did not follow in his portion of the NSABP were minor details, such as dates from the time of diagnosis to the time of registry into the study, or hormonal receptor values that had been done in other centres but were not necessarily recognized in the US. He maintains that the details he ignored had no impact on the study results, which continue to be deemed valid. The interview that follows is Poisson's response to charges that he falsified data in this important study.

"In the field of breast cancer, I have always contested a great many things. For instance, I've been fighting total mastectomies for the last 23 years. For some strange reason, the US is behind. Not only [do they have] a penchant for doing total mastectomies, but also [they fail to do] needle biopsies. Many general surgeons still do the old-fashioned surgical biopsies.

"The Americans found fault not with my way of treating patients, but with some details of my research. But I believed I understood the reasons behind the study rules and I felt

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that the rules were meant to be understood as guidelines and not necessarily followed blindly — I never intended to harm the NSABP. It is important to strike a balance between the science and art of medicine. I have more art than science. And I have learned my lesson the hard way."

Poisson also questions the significance of his actions in terms of the study results. "If you have followed the story, you will notice that they always say that results of the study haven't changed — this is not [just] Roger Poisson telling you this. . . .

"If the results haven't changed, what conclusions can you draw? Obviously, the criteria of eligibility that I did not take into consideration were small matters . . . they found [these flaws] after 2 years of investigation. More than half of my so-called irregular cases were a question of dates — in other words, the time elapsed between the diagnosis and the registration of the patient into the protocol. That has no impact on the oncological outcome, so why make such a fuss about it?

"I think they are making such a fuss because I did, no doubt, antagonize the Americans. And I should have been more rigorous — in retrospect, I should have been much more rigorous, no doubt. But these [flaws] were in my mind small things that did not have any impact on the treatment of the cancer, and they don't. . . .

"As far as the principles, well, they are something else. But the case has not been put into perspective. Who is raising all these doubts and enormous anxiety about those poor patients south of the border who wonder whether they chose the proper treatment? My patients don't ask themselves questions about whether the breast should have been removed. Their breast has been preserved and they are doing as well as the ones who had mastectomies, without the mutilation.

"Doing total mastectomies is so old fashioned — I am surprised that in 1994 we are still talking about whether radical mastectomy should be done. We are now at the stage where we talk about partial [excision of the tumour] versus no surgery at all; we are talking about medical treatment for breast cancer — chemotherapy followed by radiation. We've been treating with lumpectomy plus adjuvant chemo-therapy and radiation for 25 years now, so it's nothing new. Yet, here you have all these Americans debating whether mastectomy still has a place.

"I enrolled all these patients in the study because I was quite enthusiastic about it. We are talking about a study that was started in 1976 and went until 1984, and was a very good study. I enrolled 354 patients out of [2163] . . . in this famous protocol, which proved that breast preservation is just as good as total mastectomy. They found 6 irregularities among 354 of my patients.

"The surgeons who chose not to participate in those studies did not make any mistakes at all — they didn't take any risks, so they didn't make any mistakes. Some people say that Dr. Poisson has caused a great deal of harm because many women will now be reluctant to participate in clinical research studies. Maybe some doctors will also be reluctant to participate because it's much easier not to participate."

Poisson spent much of the interview focusing on the difficulties inherent in clinical research. "Clinical research is not all that easy, especially when you are very busy in your own clinical practice. Sometimes physicians are criticized for not explaining enough to patients about their treatment. This is fine for people who are working in ivory towers, where they don't see any women suffering from cancer.

"Not so long ago, I saw a woman who has cancer of the breast. I operated on her and then, after the operation, told her she had a malignancy. I had told her before, when I had done a needle biopsy, as well. After the operation I found that she had positive nodes in the axilla. When I told her all of this, she said, 'Well, Dr. Poisson, there is nothing too serious.' I then repeated what she had, putting more stress on the words — it is a cancer, it is a malignant tumour and the cancer has spread to the nodes and you will need treatment, chemotherapy and radiation. And the woman repeated to me, 'So it's not very serious.'

"She took the treatment, is following it and she's fine, but she does not want to hear that it was serious. Some bureaucrat would like us to cause unnecessary anguish. People who are not as deeply involved as I am, doctors who are not on the front line, they don't understand that maintaining the proper balance between good clinical care and rigid research methods is not easy.

"I was totally committed to clinical trials, perhaps overenthusiastic. How do you explain that only 2% of all breast-cancer patients in North America enter into clinical trials? It slows the studies tremendously. It took 8 years to complete the NSABP.

"Very few surgeons have seen or treated as many cancers of the breast as I have. It's not an easy field. It's not like delivering babies, where you are helping nature [and] nature is on your side. When you are treating breast cancer, nature is not on your side.

"We still don't know everything about cancer, but we have to use a lot of combined treatments — often chemo, hormonal therapy, radiation, selective surgery. Even though I am a surgeon, I never push surgery. I believe that more surgery is not necessarily better, and that goes very much against the surgical lobbying, especially in the US.

"When it comes to surgery, the Americans are very aggressive and I think it's wrong — a few years from now, I don't think even [excision] will be necessary for some breast cancers. With powerful chemotherapy, you are able to get rid of the cancer, at least make it disappear, and then radiation does the rest."

Poisson ended our interview this way, referring once again to his

patients: "My patients are very supportive of me. They support me 150%."

Perhaps being a good researcher does not automatically make one a good practitioner. I remember when my daughter, diabetic from age 9, was enrolled in a clinical trial at age 12 to test whether tight control of blood glucose would translate into fewer diabetic complications. To get me to consent to her participation, her doctor explained that getting her diabetes under tight control, especially as she embarked on her teenage years, was "her only hope." Naturally, I gave my consent.

In one arm of the study, my daughter wore an insulin pump that provided a steady infusion of insulin throughout the day; there was also a bolus at mealtimes. In another, she had to give herself four injections of insulin a day.

That doctor had the reputation, at least among her peers in endocrinology, of being a dedicated and intelligent researcher. However, I found her lacking in bedside manner, something her peers would never be in a position to judge.

My daughter had two severe hypoglycemic reactions that involved losing consciousness and resulted in nerve-racking ambulance rides to hospital. During the second hospital admission she was deposited in a crib after she had regained consciousness — a very humiliating development for a 12-year-old girl — to await the doctor. I, of course, was in the room with her.

Finally, the doctor swept in, and without even acknowledging my presence announced: "This child will have to be off the study. I don't want any deaths to confound my data." Then, with equal tact, she swept out of the room — no pleasantries, no discussion, no human contact. Nothing.

My daughter started to cry. She kept saying that she felt abandoned by her doctor. And I, as a concerned and now very worried parent, especially after the doctor had told me that intensive therapy was my daughter's "only hope," felt equally abandoned.

No doubt, the doctor's decision to remove my daughter from the study was correct, although if children do run the risk of dying from the type of treatment being tested, this should be an important parameter to consider and should be duly noted in the data. I trust my daughter's two severe reactions were included in the researcher's data.

Whatever the case, that doctor's treatment of her 12-year-old patient was abysmal, and not very healing or in any way beneficial for a child with a difficult and chronic illness. A few kind words and a discussion with the patient and the patient's parent could have made a world of difference. As it was, my daughter and I were left looking at each other, both feeling helpless and abandoned.

No doubt this researcher continues to maintain her reputation for excellence among her peers. But what my daughter needed was a human being, in addition to a research whiz. For us, this doctor has a lousy reputation as a healer — and when you get right down to it, healing and alleviating suffering is what medicine is all about. ■

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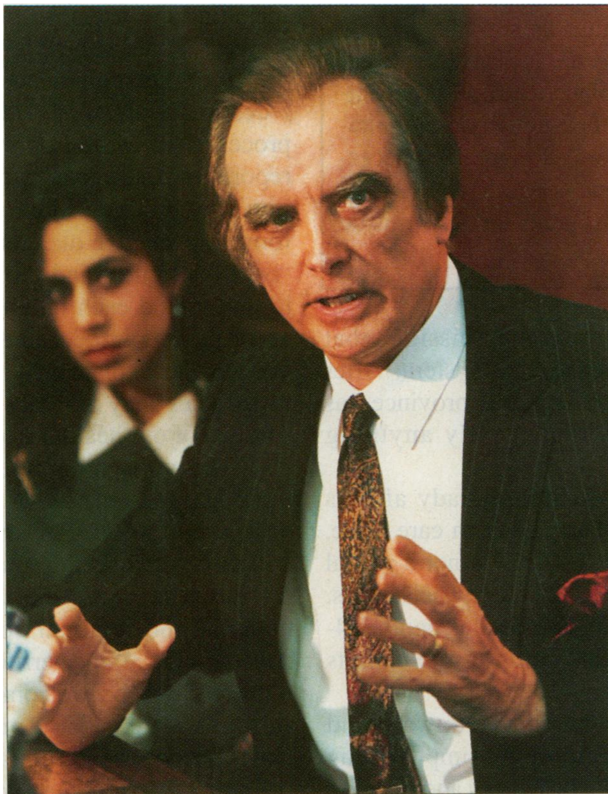

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