Letter to the Editor

The Miami results on porcine islet-Sertoli cell xenotransplantation

To the Editor:

In reference to the clinical trials of islet xenotransplantation in Mexico [1–3], Dr. Valdes-Gonzalez recently indicated that samples collected and sent to Miami for the analysis of porcine insulin levels comprised samples obtained both from patients that received pig islet transplants and subjects that did not [3]. Therefore, he is suggesting that the occurrence of positive results (presence of detectable porcine insulin seen in six samples and not, as mistakenly reported at the meeting held in Boston, in three samples) refers to the whole population, not only the population of patients that received a transplant. This information is new, and it has been only recently formally communicated to us. Prior to this information, we were under the impression that all 86 samples sent to Miami for analysis were collected from patients that received an islet transplant.

Dr. Valdes-Gonzalez also mentioned that samples sent to Miami were part of a normal double blind procedure [3]. It is therefore not apparent why we then received samples that were not always kept blinded, and in many instances we received multiple samples collected at different time points after transplantation and/or after intravenous glucose tolerance tests in subjects who were clearly identified as transplant recipients. Other samples were only identified by an alphanumeric code.

We are therefore, at the present time, not in a position to determine precisely the percentage of porcine insulin positivity in the transplanted population.

However, it is our impression that the conclusion of the International Xenotransplantation Association (IXA) Council was and is largely based on additional independent arguments, including the analysis of complementary metabolic tests (porcine C-peptide, blood glucose profiles, hemoglobin A1c levels), safety issues, and ethical issues, as well as lack of pertinent pre-clinical data. Incidentally, all our pre-clinical results using a similar approach, including pig-to-nonhuman primate transplants, failed to produce any positive outcomes (unpublished observation). In fact, both porcine C-peptide and histologic examination for insulin-producing cells were negative in all the cases (100%) of pig-to-nonhuman primate islet transplants analyzed at our institution (unpublished observation).

We would also like to state that, when the Miami group agreed to this collaboration with our colleagues in Mexico, we set up an expensive and time-consuming procedure with the precise desire to help Dr. Valdes-Gonzalez and his colleagues to gain meaningful data on their novel clinical procedure. It was with that attitude that we approached the problem, certainly not with the attitude that is inferred by the letter of Dr. Valdes-Gonzalez [3]. It is disappointing that the communications originating from Dr. Valdes-Gonzalez’s office were not always clear enough to allow the unequivocal classification of the data that the Miami group worked so hard to collect and analyze, and that generated this regrettable misunderstanding.

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References