Letters and Replies

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History of isothermic dialysis

Sir,

The historical review of Francesco Pizzarelli [1] on isothermic dialysis is a valuable review of the physiological and clinical relevant thermal processes during dialysis. The historical part of it is, however, incomplete and misleading.

Isothermic dialysis was made available by the BTM (blood temperature monitor) of Fresenius. The physics of thermal energy balance and reasoning on physiology was the basis for the development of this device, which started in 1983. When I became aware of the pioneering paper of Maggiore et al. [2] it was obvious to me that thermal energy but not dialysate temperature was the relevant parameter for the effects reported by these authors. At this time, Fresenius was a small German company without a marketing department. Decisions on development projects were proposed by research and development (R&D) and approved by the division manager. I was head of R&D for medical devices at Fresenius and proposed the development of the BTM, based on the physiological hypothesis that body temperature should be kept constant during dialysis.

The results of laboratory and clinical tests were summarized in a patent application filed on 30 October 1986 [3] (US Patent 4894164 is an English version of this patent). This patent describes all the essentials of thermal energy balancing and isothermal dialysis including temperature drops in the extracorporeal circuit, measurement of the thermal energy balance, control of body temperature or alternatively control of energy removed. It also points out that energy neutral operation is not sufficient for keeping the body temperature constant.

Curves of thermal energy balance under constant dialysate temperature condition, and alternatively under body temperature control, were published together with the physical basis and the physiological background of the BTM in a chapter of a popular textbook [4]. The same chapter in the latest edition of this book [5] also contains a physiological model of thermal control in dialysis, as well as a quantitative calculation of thermal cooling in haemodiafiltration and haemofiltration.

The papers of the authors mentioned by Pizzarelli corroborate the concept of the BTM and contribute to the understanding of the importance of thermal balance in haemodialysis, but they were only possible because a commercial device was available that was developed without the contribution of these authors.

Discussion

Scientific contributions in journals (which include novel methods and devices) are usually quoted using the names of the authors. Industrial devices are usually quoted by the name of the manufacturer. Inventors of industrial developments are rarely mentioned and I regard this as highly unfair. Unlike universities, industry does not encourage publication of novel developments by inventors. For this reason, patent applications are the only proof of innovative work for a scientist working in industrial development. Like scientific work, industrial development is rarely done by single, isolated person. In both cases, however, a leading person develops the idea and drives the project. This is usually the first author or inventor. While scientific papers are peer reviewed, patents are examined for novelty and compliance with basic laws of physics by professional patent examiners. The patent examination process is not an in-depth scientific review, but prevents redundant publication of the same idea. A working instrument based on a novel idea corroborates the ideas outlined in a patent. This shows that patent literature has the same value as papers on methods and devices published in the scientific literature.

I ask therefore, why patents are not quoted in scientific literature, although researchers know of these patents. Unlike many scientific journals, patents are freely available on the Internet and can be searched using search machines similar to Medline (see, e.g. http://www.uspto.gov/patft/index.html).

In my personal case, this neglect is not limited to the BTM. The contributions to electrolyte balancing, online HDF, dialysate filtration, blood volume control based on ultrasound, automatic dialysate flow control and various safety and monitoring systems are rarely mentioned, although they are regularly discussed in scientific papers, including NDT.

I would appreciate it if NDT were to clarify the rules for quoting patents.

This letter has not been published elsewhere. Although I am the inventor of the BTM, I have neither financial benefits from sales of this device, nor do I have shares of Fresenius or Fresenius affiliates.

Conflict of interest statement. None declared.

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