chelates in magnetic resonance imaging, more efforts should be devoted to characterize the in vivo distribution/accumulation of lanthanum upon oral administration of lanthanum carbonate.

The observation of plasma lanthanum concentrations in blood that plateau at nanomolar values does not guarantee against its deposition/accumulation outside the blood circuit. In the absence of a clear understanding of the ethiology of nephrogenic systemic fibrosis (and, in particular, of the co-causes that determine the development of the disease), it appears definitively not possible to assume the absence of risks associated to the lanthanum carbonate treatment.²

It is worth to note that the same concern has been expressed in the ‘Guidance Document for safe MR practice’ that has been recently published by the American College of Radiology: ‘There are early data that suggest that elevated levels of phosphate, iron, zinc or copper or the presence of Fosrenol (lanthanum carbonate, Shire) might serve as efficient competitors for the ‘attention’ of the chelate molecule, so to speak, and increase the concentration of free gadolinium in the patient, which might therefore increase the potential of the patient to develop NSF’ (p 13) and ‘other cations such as lanthanum, now used as lanthanum carbonate (Fosrenol) for phosphorus binding in end-stage renal disease patients, could also present similar transmetallation and free gadolinium concerns…’ (p 15).³


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A wearable hemofilter for continuous ambulatory ultrafiltration


To the Editor: In their recent article on continuous ambulatory hemofiltration, Gura et al.¹ state, 'This study describes the first human use of a wearable hemofiltration device to manage fluid overload' and claim, 'This first-ever human study of a wearable hemofiltration device indicates that its application as such is feasible.' The claims of priority and novelty embedded in these statements are simply not true. Neff et al.² in 1988, Shaldon et al.³ 1989, Murisasco et al.⁴ in 1986, and Takai et al.⁵ in 1991 have all published clinical trials involving wearable ultrafiltration devices. None were cited in the article by Gura et al. 'All four authors conducted clinical tests on dialysis patients and, although Gura et al. discuss application to cardiovascular disease their study group was the same as in earlier investigations.' The potential of using isolated ultrafiltration in diuretic-resistant cardiac failure has also been reported and was poorly tolerated in advanced cases.⁶ The published works by Neff et al.,² Shaldon et al.,³ Murisasco et al.,⁴ and Takai et al.⁵ are not difficult to find: they will turn up in a simple PubMed search or even on Google with keywords ‘wearable ultrafiltration’ or ‘ambulatory hemofiltration.’ Also, their content is highly relevant. Three of the four earlier reports describe significantly higher fluid removal rates than were reported by Gura et al.; the third describes clinical evaluation in patients not for 6 h (Gura et al.) but for 21 days (Shaldon et al.). In this latter case, the device was custom designed with wide bore fibers allowing the ambulatory patient to be anticoagulated with aspirin rather than by heparin. Investigators are certainly entitled to present their findings in the most favorable light. However, it is never appropriate to omit readily available earlier citations, and thereby blur the distinction between contributions of a pioneering and breakthrough nature and efforts, which merely represent ongoing evolution. The peer-review process is supposed to prevent this Plimsoll line from being crossed, but, in this case, regrettably, it failed to do so.


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Response to ‘A wearable hemofilter for continuous ambulatory ultrafiltration’


We thank Professors Shaldon and Lysaght¹ for their insightful letter. The concept of developing wearable devices for treating both patients with heart failure and
kidney failure is not new. The earliest attempt dates back to the work of Kolf et al.\textsuperscript{2} in the 1960s. Many nephrologists have subsequently tried to create a truly wearable device that would allow patients to carry out their normal daily living activities, or go to work, while being treated.

A ‘Google’ search using the key word ‘hemofiltration’ yielded more than 97,000 hits and in PubMed more than 5000. Thus, in the interest of brevity, not all papers on the subject were quoted. Yet, we meant no disrespect to those early pioneers on whose shoulders we all stand. Rarely does one see recognition to the scientists and innovators, who developed dialyzer/hemofilter membranes, blood pumps, and other vital equipment used in extracorporeal therapies. Similarly, very few dialysis publications, acknowledge Kolf’s original papers.\textsuperscript{3} Notwithstanding, without their seminal contributions, the current generation could not progress.

The early pioneers were confronted with many technical problems, including vascular access, anticoagulation, and both the size and reliability of any such device. Some of the earlier devices used an arterial blood supply, and those that worked only with venous blood access required a blood pump and an electrical power source. None of the papers quoted by Professors Shaldon and Lysaght detail a battery powered pump to propel blood through the hemofilter, nor describe approved safety features to monitor blood leaks and/or air bubbles.

It is only now, with miniaturization, particularly of the double channel pulsating blood and dialysate pump, in combination with accurate, reliable volumetric pumps (meeting American FDA- and European CE-approved standards), that truly wearable devices are now potentially possible.

We have recently reported our experience with both a wearable ultrafiltration device,\textsuperscript{4} and also a wearable artificial kidney.\textsuperscript{5} Patients were filmed in both trials to show that they could walk and move around independently, while still being treated, and, in one of the studies, patients walked out from the hospital, into a neighboring park, while being treated.

Thus, although we would not claim any originality to the concept of a wearable hemofilter or dialysis device, we have reported pilot studies of a truly wearable device that allows patients to ambulate, and even walk out of the hospital grounds while being treated. As such, these are landmark proof of concept studies.


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