Between December 1997 and August 1998, 31 elderly patients (mean age 73) had aortic valve replacement using a Labcor stented porcine tricomposite bioprosthesis (Labcor Laboratories, Belo Horizonte Brazil). Doppler echocardiograms were performed at varying times in the postoperative period (4 days to 10 months). In the first week after implant four patients were found to have a high peak gradient across the left ventricular outflow tract (45, 55, 71 and 80 mmHg) with commensurate low effective orifice areas.

Following the mandatory reporting of this to the Swedish Health Ministry, the implant programme was stopped, and the subsequent media involvement ensured that there was wide publicity to the medical community and general public. A subsequent detailed analysis of the results illustrates the complexity of issues surrounding in vivo assessment of valve function and reveals some of the pitfalls that may occur when a new device or technique is introduced into clinical practice.

Our conclusions are:

1. Early non-invasive analysis may be misleading in patients with marked left ventricular (and outflow) hypertrophy and a normal or raised ejection fraction—in which circumstances a dynamic outflow obstruction can occur after relief of aortic stenosis [1,2]. This obstruction can take many weeks to resolve. This occurred in two of our patients.

2. Coexisting pathology must always be fully assessed. One patient proved to have severe paraprosthetic regurgitation that was not noted at discharged, but eventually found on invasive study. At redo valve replacement the porcine valve appeared normal.

3. One patient with a heavily calcified aortic root had a 23 mm valve inserted with difficulty. The valve was seated at an angle—a known cause of creating difficult echocardiographic assessment. The patient also had a body surface of >2.0 m [2], indicating possible biological mismatch.

In the clinical setting, it is important to investigate extreme values to determine why these patients deviate from the norm. Such individuals, if not recognized appropriately, can mislead and misinform. Further investigation may reveal that poor function is attributed to patient condition or limitations of the diagnostic methods, rather than device failure. Our analysis revealed that the unexpected rise in gradients as seen on echocardiographic examination was not device related. The Labcor stented porcine valve used in this series of patients was not defective and the performance of normal functioning Labcor valves was equivalent to that of other porcine bioprostheses [3–5].

The regulatory environment often dictates reporting and sharing of information. However, our experience emphasises the need for understanding data as it is reported. This experience illustrates the complex interrelationship between regulatory and legal demands, general clinical experience and the influence of a cautious clinical attitude, and the need to seek the truth in assessing a new technique or device by the fullest possible analysis.

References