ABSTRACT: Endotoxin-associated Sterile Peritonitis Observational Study (e-STEPS): Safety Findings

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BACKGROUND
From September to December 2010, a recall of peritoneal dialysis (PD) solutions (1 Dianeal and 2 Nutrineal lots) was initiated in Europe. These 3 recalled lots (manufactured at 1 site in Ireland) were related to elevated endotoxin levels and associated with increased sterile peritonitis (SP) spontaneous reports.

OBJECTIVES
Describe safety outcomes in PD patients with endotoxin-associated SP (e-SP), no peritonitis (NoP), and bacterial peritonitis (BP) over a 12-month period.

METHODS
A post authorization safety study was conducted using a retrospective chart review study design in 12 European PD clinics (Germany, Hungary, Netherlands, Portugal, United Kingdom). e-SP and NoP patients used 1 of 3 recalled lots; BP patients used Baxter PD solutions in Viaflex containers from the same manufacturing site as the recalled lots. Safety data were collected up to 12 months pre/post index event. Safety was evaluated by assessing peritoneal membrane function (i.e. dialysate/plasma creatinine [D/P Cr]), clinical outcomes and presentation/management of the index event. Statistics were mainly descriptive.
RESULTS
Population included 127 patients (46 e-SP, 38 NoP, 43 BP). 50% were female and mean age was 64 ±15 years. 95% were on continuous ambulatory PD at index event, 89% of patients had 1 or more serious adverse event (SAE); 393 SAEs were recorded overall. 89% of e-SP and 86% of BP patients recovered within 1 month of index event. Overall, 7% of patients died with no differences in fatality across cohorts. Within 12 months post index event and across cohorts, no significant differences were found in D/P Cr. Compared with e-SP and NoP cohorts, more BP patients permanently transferred to hemodialysis (HD) (37% vs. 8.7% e-SP and 0% NoP), developed peritonitis (51% vs. 17% e-SP and 13% NoP) and were hospitalized (61% vs. 41% e-SP and 40% NoP).

CONCLUSIONS
While majority of patients had 1 or more SAE, e-SP and NoP patients did not appear to have clinically meaningful long-term effects from recalled lot exposure on peritoneal membrane function or clinical outcomes; BP patients appeared to have more long-term clinical consequences.