In the past 2 years, we have carried out 152 consecutive cases of large balloon dilation of the papilla after full length sphincterotomy in our center. The procedure was undertaken in patients with normal structural anatomy and large (> 12 mm) unretrieved biliary duct stones, using balloon catheters (CRE Esophageal/Pyloric maximum diameter 15, 18, or 20 mm; length 5 cm; Boston Scientific, Natick, Massachusetts, USA). We experienced three cases of perforation (2%) related to balloon dilation during this period. All three cases involved middle-aged women hospitalized for cholelithiasis.

The first perforation was discovered on cholangiography performed immediately after the dilation, which showed leakage of the fluorescent contrast medium around the duodenal wall (Fig. 1). A plastic stent was immediately placed to contain the leaking bile and the patient sent for urgent computed tomography (CT). The other two cases manifested within the first 24–48 hours. There was no sign of perforation on cholangiography and the patients remained afebrile and haemodynamically stable. However, they complained of a dull abdominal pain in the epigastrium, and laboratory findings indicated slightly raised levels of inflammatory markers (C-reactive protein and white blood cell counts). Plain radiographic examination did not suggest presence of free air and the patients were referred for CT, which revealed pneumo- and retroperitoneal fluid collection in both cases. There was only a small amount of contrast leakage in the first case (Fig. 2 and Fig. 3). All three patients were managed conservatively with antibiotics, placement of nasogastric tube, and close medical monitoring, and were discharged within 10 days. There were no medical concerns during the follow-up period.

To our knowledge, remarkably low rates of perforation (0.2%) [1] have been observed worldwide in studies using large balloon dilation of the papilla after sphincterotomy in patients with normal anatomical structures [1–4]. The rare cases that have been reported until now were treated conservatively [4, 5]. Of course, large balloon dilation of the papilla after full length sphincterotomy is a new method, and many related issues are still under evaluation. However, our data suggest that perforations may be a more frequent complication but are not reported as such because they may be subclinical or misdiagnosed. Vigilance on the part of medical staff, appropriate use of radiological imaging, and close monitoring may help resolve this difficult judgment call, and spare the patient from undergoing unnecessary and difficult surgical procedures while preventing serious and occasionally fatal sepsis.

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Fig. 3 Computed tomography (CT) scan depicting free air in the peritoneal cavity and retroperitoneum (white arrows): a patient 2.

b Patient 3.

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