BRITISH SOCIETY OF GASTROENTEROLOGY

Executive Summary

Response to Coroners Regulation 28 Report Request: Stephen Whitehead RIP.

The BSG notes HM Coroner's request under Regulation 28 and is pleased to file the attached response on behalf of the Society.

Expert opinion is provided by the Endoscopy Section of the BSG, taking views from individual national experts. In response to your questions we note: -

1) Biliary stenting is common and there are consensus guidelines on good practice produced by the BSG, NICE and other bodies.
2) Levels of expertise and local practices vary within guidance (dictated by local expertise and systems and services)
3) This case highlights the need for basic adherence to the principle of definitive bile duct stone clearance which should be the goal in all patients: long-term stenting is not appropriate except in circumstances of extreme comorbidity.
4) There will be variation in the approaches to bile duct clearance and timing of surgery between Units (expertise dependent) but this should not preclude
   a) clear communication between medical and surgical teams (if necessary through a formal MDT process)
   b) clear communication with the patient and patient's family of the management plan
   c) clear recording of the next step of the technical pathway by the ERCPist performing the stent insertion (backed up by a robust record of stent placement and the interval and need for patient recall)
5) In the views of the Society a National Stent Registry would *not* contribute to the above.

Separately we should point out that reduction in variation in practice is one of the objectives of the Get It Right First Time (GiRFT) initiative. The first National Gastroenterology Lead for this is now in post and will be working closely with the BSG on matters of best practice and reduction in practice variation.

Dr Cathryn Edwards MA D.Phil FRCP
BSG President

Re: Stephen Whitehead DOB 18/04/1960 died 08/02/2018 at The Royal Oldham Hospital

Whilst the devastating outcome for Mr Whitehead is unusual we recognise that the bile duct stone disease is the most common indication for the more than 50,000 ERCPs performed in the UK each year, of which a significant proportion will result in the insertion of a biliary stent. The use and monitoring of biliary stents is therefore an important issue for patients and endoscopy service provision. Following consultation with colleagues within the BSG important we feel that there are a number of issues raised, for which we also have proposals:

1. **Communication**. It is not clear from the details provided whether clear and explicit written information was provided to the patient, GP, and surgical team that a stent had been inserted, the necessity of subsequent removal, and the timeframe for this to happen. In writing to endoscopy units/BSG members we will emphasise the importance of this measure, and the need for a clear directive on every ERCP report which (as is standard) is given to each patient and their doctor.

2. **Ownership of management.** A well recognised issue within ERCP practice is a perception (and perhaps reality) that the ERCPist is doing the procedure 'for the surgeons', with overall management (beyond the ERCP itself and immediate post-procedure period) remaining the responsibility of others. This is understandable, given that on-going decisions concerning timing of cholecystectomy or other biliary surgery will directly impact on timing of (or need for) further ERCP. The summary of the case alludes to this issue, and may certainly have been an issue in the patient being lost to follow up. We propose that a plan for repeat procedure (e.g. at 3-4 months) should be set at the time of ERCP. Whilst this may need to be cancelled/amended, according to the unpredictable nature of changing patient circumstances (e.g. intervention, comorbidity), it may act as an important 'safety net'

3. **Database of stents.** We completely agree that a clear record of when a stent has been placed, and when this should be removed or changed, is important. We feel this should be within the ownership of the endoscopy unit that has inserted the stent. This may be a formal database or a facility within the electronic endoscopy reporting tool, but should be contemporaneously entered at the time of the ERCP, with a clear plan as to timeframe for patient review/repeat procedure. Crucially the system should allow easy, rapid and demonstrable review of all patients who have undergone stenting within an extended time period.

After careful consideration, we do not feel that the answer is a national database of biliary stents. This would be unwieldy and require significant additional manpower and infrastructure to police. The vast majority of patients will have their care in one locality and, as suggested in the report, shortcomings in local arrangements of care, including communication between local teams, GP and patient, were the fundamental issues highlighted here. Although the National Endoscopy Database (NED) has now been introduced nationally, it is important to record that this does not allow individual patient tracking, and could not act as a proxy database of biliary stents. The BSG and JAG are however in discussion concerning adding the use of a stent planning/recall database to the key performance indicators (KPI) within its national standards framework, and incorporating it into the ISREE (Improving Safety and reducing Errors in Endoscopy) programme. This topic will be formally discussed at the BSG Endoscopy Committee in October.

4. **Overall management of complex biliary stone disease.** Although not specifically addressed in the coroner's report we would raise a concern that the patient's disastrous outcome with respect to cholangitis/retained stent and 'lost to follow up' relates in part to the overall management of complex stone disease. It appears that the patient underwent a lap chole with a 'large gallstone' still within the bile duct, which would be an unusual approach. It is not clear from the report that there was an overall plan of management to address removal of the bile duct stone. Recent BSG and NICE guidelines on gallstones make it clear that definitive bile duct stone clearance should be the goal in all patients, and that long-term stenting is not appropriate except in circumstances of extreme comorbidity. This is supported by published data. With the increasing availability of advanced techniques to achieve stone clearance, and all hospitals now sitting within HPB networks, all patients with complex stone disease should be referred to a centre experienced in management, if not available locally.

We would be extremely happy to discuss these issues further, but hope that they address many of the concerns raised by the coroner.
Yours sincerely,

Dr George Webster
VP (Endoscopy) British Society of Gastroenterology