



BRITISH SOCIETY OF
GASTROENTEROLOGY

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Mr Robert Simpson
Assistant Coroner
HM Coroners Service
County of West Sussex

12 July 2021

Dear Mr Simpson

Regulation 28 Report to Prevent Future Deaths - in respect of the investigation into the death of Anne Bradley, 23rd May 2021

Thank you for asking the British Society of Gastroenterology (BSG) to reply on the matters raised by the coroner in the Regulation 28 Report on the case of Anne Bradley. The report concerns the death of Anne Bradley who underwent a colonoscopy and was found to have a resectable tumor at 40cms from the anal margin, which was tattooed and subsequently resected. Unexpectedly, the resection specimen contained no evidence of malignancy. Subsequently a further tattoo was located in the mid transverse colon marking the site of the cancer which was resected. Unfortunately, Anne Bradley died of postoperative complications. The issue was raised as to whether a magnetic endoscopic imaging device (MEI) such as the Olympus Scope Guide or Pentax Scope Pilot could have prevented her death by localising the tumour more accurately, and whether these devices should be used routinely.

We would make the following comments.

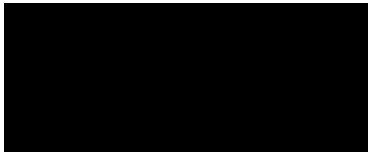
1. Ultimately it is always the responsibility of the surgeon carrying out an operation to identify and remove the correct section of bowel. Distances described at colonoscopy are always potentially subject to significant error, dependent on the amount of colonoscope inserted. The instrument can "loop" and as the colon itself is elastic, so measurements can vary immensely. It is not unusual to examine a resection specimen and then make a further resection. Anne Bradley's death from post-operative complications mainly reflects the quality of her postoperative care, and to imply that it relates solely to the lack of an MEI is unwarranted.
2. The tattooing of a polyp or tumor is standard practice because distances measured at colonoscopy can vary immensely. It should be noted that colonoscopists often tattoo polyps over 1cm in size so that their position can be noted and the site identified again if the resection of the polyp is thought to be incomplete. Polyps are often multiple, so it is common for an individual patient to have a series of tattoos placed over the course of their lifetime.
3. The implication that the unintentional tattooing of another section of colon is common, is not correct. The published evidence on the frequency of accidental injection of another section of the bowel should be reviewed. It is well accepted, however, that the position of a tattoo is only an approximate indicator of a polyp or tumor. Tattoos are often placed on the distal side of a tumor. The ink often spreads

and therefore they can only offer at best an approximate indication of the tumor position. They are, however, more accurate than any other marker or measurement that is available at present. Most surgeons are aware of these issues, and it remains, therefore, the responsibility of the surgeon carrying out the operation to identify the correct area for resection, and to make sure that the correct tattoo has been seen. It is also their responsibility to ensure that adequate margins on either side of a tattoo have been taken, to make sure that the lesion has been included. For this reason, and because it is well recognised that precisely localising the position of a tumor can be very difficult, many surgeons would have recolonoscoped the patient preoperatively to determine to their own satisfaction the exact position required for the resection, and it would have been useful to determine why this was not carried out in Anne Bradley's case.

4. An MEI, does not provide precise localisation of a tumor as appears to have been suggested. MEIs can certainly help to negotiate a difficult colon, they can demonstrate if loops are formed in the scope and whether they have been removed, and for these reasons, MEIs are invaluable in training and also improve comfort for the patient. In the case of bowel cancer screening, where patients are voluntary and asymptomatic, MEIs have been extensively used to ensure the maximum success rate in visualising the whole colon. Their use in bowel cancer screening, however, was not primarily to provide a precise localisation of polyps or tumors which is why tattoos are extensively applied.
5. Most authorities agree that the only precise landmarks in the colon are the appendix orifice, the ileocecal valve, and the terminal ileum. If the cecum has been successfully achieved and the scope is straight, the colonoscope usually adopts a "question mark" shape on the MEI. As soon as the colonoscope starts to be withdrawn the appearances become very variable, and also depend on the shape of the patient's colon and the patient's position. Patients are frequently rolled from the left lateral position to their back and even occasionally prone. The shape of a colonoscope on an MEI can vary enormously depending on these conditions. Only general statements can therefore be made about the position of a tumour or polyp. In the case of Anne Bradley, it might have confirmed that the tumor was in the mid transverse colon but this cannot be automatically assumed. An MEI would probably have distinguished between the sigmoid colon and the transverse colon, but an MEI would not be able to precisely localise the position of a tumour within, for example, the sigmoid colon itself. For this reason, the position of any lesion on an MEI should always be regarded as approximate. This is why correct tattooing, rather than MEI, is the key method to localise a tumor.
6. A paper by ████████ et al. *Colonic tumour localization using an endoscope positioning device*. Eur J Gastroenterol Hepatol 2011;23:488-9, did suggest that MEI can improve accuracy of location to the correct segment of bowel, but as far as we are aware compulsory use of MEI in all colonoscopy is not recommended by any published evidence based guidelines because so many other factors, as we have indicated, can have a bearing on tumour localisation in an individual case.
7. Whilst it is possible that an MEI might have provided some extra information in this particular case, it is quite erroneous to infer that an MEI would assist in the exact location of a lesion in *all* cases, and to suggest that they should be used as a mandatory requirement greatly overstates their utility for precise the localisation of pathology. It would, therefore, be wrong to make a generalised recommendation on the use of MEIs based on this particular case.

8. It is much more important that both the physicians and surgeons in a unit agree a common tattoo protocol. One widely used example is The St Marks protocol. <https://www.stmarksacademicinstitute.org.uk/content/uploads/2020/12/Tattoo-protocol-v15.pdf>
9. MEIs are manufacturer specific, so the “Scope Guide” will only work with Olympus scopes and “Scope Pilot” with Pentax scopes. Many units use Fujinon scopes, and whilst there was a similar system available in the past I am not aware at present whether it is still marketed. Mandating the statutory use of MEI effectively sanctions compulsory purchase without any competition, and might preclude a number of other commercial companies that manufacture scopes. The cost of an MEI is very significant, and therefore a mandatory obligation that they should be used in all cases could run into a cost of millions of pounds without there being a clear benefit in all cases. **It could be argued for, for example, that employing more staff to carry out colonoscopies so that patients do not wait have to wait so long, might save many more lives then mandating a particular piece of equipment on the basis of a single postoperative death.**
10. One should also emphasise that a death from postoperative complications, usually raises questions about the care that the patient received *after* the operation, or their underlying health before surgery. To imply that use of an MEI might actually have prevented Anne Bradley's death from postoperative complications may be an overstatement of cause and effect.

Yours sincerely



President, British Society of Gastroenterology