

Questions and Answers session - EPISODE 3 - 14th May 2020

Please note that the following text is not an accurate reproduction of the minutes of the online session. They have been extensively edited to make it more informative and useful to readers.

Do you think the findings of this study are applicable to current UK practice and particularly Yorkshire? (external validity)

Practice in most places across Yorkshire and the Humber is not to perform routine on table cholangiogram for complicated gallstone disease. The findings of this study may not therefore be applicable to our daily practice. However, if a cholecystectomy is expected to be difficult and a cholangiogram is thought to be helpful, the results of this study may be relevant.

Why was the study only 'single blinded'?

It would be unfeasible to blind the person performing the procedure or assessing the imaging.

What does allocation concealment mean?

It means that the random sequence is concealed from investigator(s) enrolling patients into the study.

Explain 'non inferiority'

A non-inferiority trial is one where the 'novel treatment' is not substantially worse than the standard (or control) intervention. It is usually employed in situations where the novel treatment may have other advantages such as lower side effects, lower costs, improved compliance or convenience. The aim of this paper was to determine whether fluorescence imaging is non-inferior to X-ray cholangiogram at identifying the junction between cystic duct and main biliary tree. If this is the case, fluorescence imaging may then be introduced into clinical practice as there are other intrinsic benefits compared to X-ray cholangiogram; particularly the absence of radiation exposure and avoidance of cystic duct cannulation.

How can you assess external validity of this paper?

External validity (or generalisation) of this paper (or any other) is assessed by studying the PICO components of the trial - population, intervention, comparator and outcomes. If the trial is conducted on a technology (that is available, feasible to use and relatively inexpensive) in improving clinical outcomes (that are clearly defined and relevant) in a study population (that is similar to what is seen in routine clinical practice) when compared to a control arm that resembles current practice; then the trial is considered to have high external validity.

Can you explain the principles behind fluorescence imaging? How was the fluorescent dye administered?

A fluorescent contrast agent is administered intravenously ideally a few hours before surgery. The agent itself binds to plasma proteins, taken up by the liver and is excreted preferentially - if not exclusively - via the biliary tree. Fluorescent light (usually in the NIR range) emitted by the agent is then used to image the biliary tree.

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