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Created: 14 Feb 2021, 12:10 p.m.

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Abstract

Title of Study	Risk factors for acute pancreatitis post EUS and sampling.
Abstract and methodological description	Introduction Endoscopic ultrasound (EUS) is the modality of choice for sampling of lesions in the pancreas. EUS is a highly specialised endoscopic discipline and has a recognised complication rate even in the best of hands.[1] Perhaps one of the most feared complications is acute pancreatitis although this is quoted to be in the range of 0 - 2%.[2-6] Current data based on small studies did not identify any specific risk factors for acute pancreatitis related to the lesion sampled or

procedural variables. Hyperamylaseamia has been reported in up to 5% of patients undergoing EUS with FNA however acute pancreatitis was not experienced in all of these individuals. Hyperamylaseamia was associated with biopsy of a cystic lesion and the use of a 19 gauge needle.[7] Most studies have focussed on prevalence of post EUS morbidity and have not looked at other potential risk factors for the development of acute pancreatitis post EUS and biopsy.[8] There are also no data concerning fine needle biopsy (FNB) needles which theoretically could have a higher risk of causing post EUS acute pancreatitis. Whilst the risk appears to be low, acute pancreatitis can adversely alter the outcome for some patients and is therefore important. Furthermore, the routine use of rectal NSAID's has altered to risk profile in patients undergoing ERCP[9] and rectal NSAID's have also been used to reduce the risk of acute pancreatitis following EUS guided radiofrequency ablation.[10] Development of post EUS acute pancreatitis can change a lesion from being potentially resectable to unresectable. Identification of risk factors that may enhance the chances of developing post EUS pancreatitis will inform a study of the use of NSAID's in this group of patients.

Patients and methods
Prospective analysis of patients undergoing EUS and sampling of pancreatic lesions in a muticentre centre fashion in the UK. Each centre will be issued with unique access to the RedCap database to upload each patient undergoing EUS and sampling providing the largest prospective collection to date. EUS is a complex and specialist procedure in the UK and not routinely performed in all hospitals. The centres included in this study all perform >200 EUS per year and therefore will provide a minimum of 40 cases into the database. The largest centres perform >1000 procedures per year and will provide at least 300 cases into the database.

For each patient undergoing EUS guided sampling and the following variables will be recorded using RedCap:
Age, sex, lesion type (solid, cystic or mixed), lesion site (head, body or tail), lesion size (in mm), FNA or FNB, needle size, number of needle passes, smoking history, alcohol history, previous history of pancreatitis (Y/N), main pancreatic duct diammeter on CT and the presence of atrophy of pancreas

distal to the lesion.
Development of post EUS and biopsy pancreatitis will be determined by using local electronic recording systems and a telephone call at 7 days to determine whether there have been any complications since the procedure. This will also be recorded on RedCap.
Final histology will also be recorded.

Analysis
Initial analysis of 1000 cases will yield around 20 - 40 individuals developing post EUS and sampling acute pancreatitis. This may not be sufficient to identify specific risk factors and therefore further cases (up to 2000) may need to be analysed. Univariate and subsequently multivariable analysis will be performed to identify independent risk factors for the development of post EUS and biopsy acute pancreatitis.

Justification for funding
The main funding requirement is for running and maintaining the RedCap database as part of this study. This will involve monthly updates to all sites involved, support for issues relating to data input and feedback as well as final collation and data analysis. Each site will run this study using clinical fellows and local clinical staff to reduce costs. The total cost is therefore £6,952.

Output
This data will be used to identify those at highest risk for post EUS and biopsy acute pancreatitis. This will then inform a prospective randomised study for assessing role of NSAID's in prevention of post EUS and sampling acute pancreatitis. Abstract submission and publication of a full paper would be expected.

References
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Timetable

Name	First patient entered
Date	01/09/2021

Name	Last patient entered
Date	01/09/2022

Funding

Name	Set up fees
Amount	2204.0

Name	RedCap fees, research support
Amount	4748.0

Details of ethical approval

Full ethical approval will be obtained. This will be completed once funding has been secured.

Institutional approval information

Newcastle Upon Tyne Hospitals NHS foundation Trust have agreed to sponsor the study.

Declaration

Confirm Declaration: Yes

Head of Department

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