

Ruth Reeve

CoRIPS Research Grant 168

£3,034 awarded

Title: Understanding patient experience of premalignant pancreatic cystic lesion surveillance to inform the development of an intervention to improve current care.

Principle Aim

To better understand the experiences of patients under surveillance for pancreatic cyst lesions (PCL) and identify the information and support needs of patients under surveillance for PCL

Primary research question

What are the experiences, information and support needs of patients with incidental asymptomatic premalignant pancreatic cystic lesions who are undergoing imaging surveillance?

Outcomes

The outcomes of this qualitative study will be thematic analysis reporting themes and sub themes addressing the research question and aim, providing new knowledge of the patient experience of imaging surveillance for a premalignant condition to pancreatic cancer.

These findings will identify what methods are required to support patient needs following diagnosis and during imaging surveillance, informing a grant application to develop interventions to improve the current care.

Review of literature and identification of current gap in knowledge

Pancreatic cystic lesions (PCL) were once considered rare findings (1). Now they are becoming diagnosed more commonly with the increased use of cross-sectional imaging and improved technology (2). PCL are most commonly reported incidentally in asymptomatic patients, where up to 20% of MRI scans identify these lesions (3).

PCL are important to identify and monitor due to their increased risk of developing into pancreatic cancer (4), where treatment for pancreatic cancer often involves extensive surgery which has a significant morbidity rate (5). Despite patients with PCL having this increased risk of developing pancreatic cancer, the

rate of malignant change is low (4); so management often involves surveillance to identify which PCLs may become suitable for treatment.

When developing a surveillance system for patients to enter it is important to identify if patients are likely to develop cancer worries so that suitable interventions can be built into surveillance programmes (6). However, there are no published qualitative studies exploring the experience of surveillance for premalignant pancreatic cystic lesions and therefore it is unknown what the current experiences are and whether patients have any unmet needs.

Findings from studies that have looked at other patient groups under surveillance for low risk or precancerous conditions, such as prostate cancer and cervical dysplasia, demonstrate that anxiety, distress and depression are frequently reported in patients, where patients report feeling in a “threatening situation” (7-10). In addition to such experiences being reported, there is also growing evidence of unmet patient information and communication needs in multiple patient groups under surveillance for precancerous and low risk cancers, such as prostate cancer, Barrett’s oesophagus and cervical dysplasia (11-14).

Results from a literature review performed prior to this application looked at experiences of patients under surveillance for premalignant and low risk cancers. No studies that explored the experiences of PCL patients were found within the review search. Studies focussing on other patient groups demonstrated that patients often respond to their diagnosis and surveillance in a number of ways. Responses were often dependent on patient groups and diagnosis; common factors that affected patients’ experiences included: information on diagnosis and surveillance (13, 15), communication of diagnosis and surveillance results (12), and interactions with health care professionals (16).

Although the literature review did not reveal any studies of PCL surveillance, uncertainty was identified within other qualitative studies of patients under surveillance for precancerous and low risk cancers (14, 17). Uncertainty for patients arose from 3 main domains: having an unknown prognosis (18), uncertainty of progression/cancer related death (19), and being in an ill status but feeling healthy (20). Such issues are thought likely to occur in the PCL population due to similarities in disease management.

Anxiety has been historically reported in studies looking at patients’ experiences of active surveillance (21). However, more recent longitudinal studies indicate that over longer periods of surveillance, the levels of anxiety tend to decrease (22). Qualitative studies within the literature review of other patient groups identified that stress and uncertainty are often time-based, with fears that were specifically induced by surveillance related activity (17, 23). Unlike other patient groups, where over time the risk of cancer developing reduces or surveillance

only occurs for a particular time period (20), patients with PCL have surveillance for an unforeseeable length of time because the risk of developing cancer does not change over time (2). This may mean that the levels of anxiety may not decrease over time as seen in patient groups like prostate cancer. In addition, the surveillance management usually involves yearly imaging, with long periods of inactivity between tests and potentially long waits for results. This may mean that test-related anxiety may differ from that of patients who have more frequent surveillance activity, although this has also not been addressed in the population of patients with PCL under surveillance.

Support and self-management strategies were varied in reports by patients under surveillance. Patients felt the relationship with the clinical team made a substantial difference in their confidence in their surveillance experience (18). Support from friends and family was met with different responses for patients, where some found family and friends unsupportive (24). Patient self-management strategies included living a normal life (17), or doing something extra such as developing healthy lifestyle changes or seeking further information to manage the uncertainty (25). Patients also used problem-focused strategies to cope following diagnosis and surveillance: the most common ones identified in patients under surveillance for premalignant and low risk cancers were acceptance and avoidance. Patients either accept the management, feel like they have a sense of control by having the condition monitored (23), or avoid the cancer status to minimize their concerns (19).

With reports in other patient groups identifying unsatisfactory experiences and unmet needs, it is expected that patients with PCLs may experience issues similar to those patients with similar precancerous or low risk cancerous conditions such as prostate cancer. But the differences in prognosis when PCL's develop can lead to significantly different outcomes than for other patient groups such as prostate cancer. Treatment for those with PCLs holds a higher risk and disease progression has a poorer outcome: pancreatic cancer is one of the top 5 causes of cancer-related deaths, with a poor 5-year survival rate that has not significantly improved over the past 40 years (6, 26, 27). This study aims to understand the experience and needs for patients under PCL surveillance. The results will contribute to the understanding of a currently under-researched group of patients, and will inform the development of an intervention to improve the experience and care pathway for these patients.

Methodology

To explore experiences and perceptions of PCL patients under surveillance a qualitative approach will be taken. Qualitative methodologies promote exploration and description of the individual experience with in-depth, thick data collection exploring the phenomenon under investigation and identifying initial

themes. Interviewing has been described as the most suitable method for collecting data when seeking to understand perspectives of individuals contextualized within their own history and/or experiences (28).

This study will be undertaken with an underlying subtle realist position. Where this study seeks to understand patients' experience in a complex environment, the researcher is aware of the involvement of their own assumptions and therefore interpretation is merely a representation of the "truth". With this worldview that knowledge of reality can never be certain, a pragmatic approach to design has been adopted using critical criteria for assessing the plausibility of the findings, credibility of the methods and relevance of the issues. In keeping with this theoretical foundation, inductive thematic analysis is the method chosen, using rigorous methods including double coding, negative case in an attempt to reduce any potential bias.

Method

Using a qualitative approach to identify the experiences of patients, the study design will entail cross-sectional face to face (or telephone) qualitative audio recorded interviews with approximately 30 patients under surveillance for premalignant cystic lesions of the pancreas. To ensure the sample captures representative experiences of the current pathway for PCL surveillance, a purposive sampling strategy will be used. The size of the sample will be defined by data saturation, data collection will stop when no new information or themes have emerged in 3 subsequent interviews (29). Recruitment will occur in 2 sites that use different surveillance methods: Portsmouth Hospitals NHS Trust (PHT) and University Hospitals Southampton (UHS). All suitable patients will be discussed and reviewed at the local weekly hepatobiliary multidisciplinary team meetings (MDT). The local hospital research teams will receive a copy of the MDT where suitable patients will be identified to approach and be invited to participate using methods developed with PPI guidance. Study posters developed with the PPI team will be advertised in suitable hospital environments. In the event of recruitment issues patients will be invited to participate in the study by letter.

As the research aims to explore the experience of surveillance over the entire period of surveillance a cross-sectional approach will be used where patients will also be recruited at different time points within the surveillance pathway including: following diagnosis, following first surveillance test, and following a longer period of surveillance (minimum of 2 years). In addition, recruitment using maximum variation sampling will be used with the aim of capturing a range of different patients such as: range of ages and ethnicity, with an equal number of male/female participants.

	PHT/ UHS (CT)	PHT/ UHS (MRI)	PHT (US)	Total
Following diagnosis	3+	3+	3+	9+
Following first surveillance	3+	3+	3+	9+
During surveillance (>2 years)	3+	3+	3+	9+
Total	9+	9+	9+	27+

Following identification and invitation by clinical/research staff, patients must fully consent prior to taking part in an interview, which will last approximately 1 hour. The inclusion criteria state that suitable participants must be under surveillance for PCL, English speaking and able and willing to provide informed consent. If patients are unable to give informed consent, the reason for not being included in the study will be discussed with the patient and explained. Following interviews at the participants' desired location, the transcribed interviews will be analysed using thematic analysis and constant comparison, identifying and analysing themes within the rich qualitative data and across subgroups of patients (30). Results will be combined with findings from the literature to develop recommendations for improvements to current care and interventions that could improve care for PCL surveillance patients.

There is no direct risk to participants taking part in the research study. Indirect risks include:

Emotional distress: As the interviews involve talking to people about their experience of a disease diagnosis and surveillance, there is the potential that the in-depth nature of the questions may invite participants to express sensitive emotions. If this occurs, the researcher will keep the participant's wellbeing in mind, pause the interview and confirm with the participant whether they would like to continue or end the interview. If the participant becomes continually distressed then the researcher will ask if they can contact someone to support the participant and appropriate emotional support will be sought or signposted.

Identifying gaps in participant knowledge: when exploring the experience of a potential cancer diagnosis there is the potential that some participants may not be aware of the diagnosis and answering questions may potentially cause upset to them. To reduce the chance of this occurring, participants will be provided with information leaflets developed with PPI input that will include contact information of healthcare professionals who will be able to answer any health concerns that they may have. If during interviews patients ask the researcher questions about the gap in knowledge regarding their condition they will be given the information and signposted to appropriate sources for further information.

Unnecessary anxiety: due to the possibility of patients being unaware of their risk of cancer, this term will not be used within participant information or interview

questions and will only be mentioned if raised by participants during the interview.

Safeguarding risks: if during the interviews participants raise a concern about themselves that the researcher considers a safeguarding issue then the researcher will act according to the HCPC code of conduct and raise the concern to an appropriate team member or safeguarding group.

Potential Impact of the study

Potential benefits will be an improved understanding of patients under surveillance for PCL, and potential recommendations for improvements to management. Based on study results, early development and testing of a care package for those diagnosed with PCL can be developed. With escalating numbers in this patient group, clinicians are increasingly required to support the PCL population. By identifying causes of distress, anxiety or depression, suitable information interventions and/or communication aid for staff can be developed for patients, meeting patient needs as highlighted in recent pancreatic cancer NICE guidance (26). Referring Clinicians and Radiographers who perform aspects of surveillance and communicate with PCL patients are often not specialists in this area, so developing tools and information aids will also help these clinicians to support their patients. Identifying unmet patient needs and developing information and/or communication aids to improve such gaps, will lead to more effective use of time for referring clinicians, cancer nurse specialists and pancreatic surgeons.

Dissemination

The updated NICE guidelines (26) recommended qualitative research for patients with, and at risk of, pancreatic cancer. The findings from this study will be submitted for publication in peer reviewed journals to maximise impact (Radiography, BMJ). In addition, supplementary papers will be submitted to reach wider audiences and impact surveillance practice (e.g. Imaging and Therapy Practice). Results from the interviews, followed by development of the proposed intervention will be submitted as a feasibility study for future post-doctoral work.

I intend to share results and plans for future research by presenting at the annual regional MDT HPB event in Wessex, ensuring clinicians in the area are aware of the findings. Results will be shared nationally at conferences such as UK Radiology Conference and international conferences such as the European Society of Gastro Abdominal Radiology. By sharing the research at its development stages, as well as at the completed stage, I envisage the key stakeholders in management of these patients will become suitably invested to

create lasting improvements for this group of patients. In addition to regional dissemination, I intend to be proactive in submitting reports and presentations to suitable professional outlets such as professional journals, conference presentations as well as dissemination via collaborating and associated research networks. The study PPI group will inform the development of suitable methods to share such results with patients, including media content and participant information. Social media provides an effective medium to share and spread the findings from this body of work not only in educational and professional arenas, but also for patients to see results. Any presentation, publication and event where the study will be discussed will be advertised through sites such as Twitter, university, hospital and professional body/organisational social sites.

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