National Institute for Health and Clinical Excellence

315 – Laparoscopic distal pancreatectomy

Comments table

IPAC date: 10 November 2006

Consultee name and organisation	Section no.	Comment no.	Comments	Response Please respond to all comments
BUPA	1 – Provisional recommendations	1	BUPA has not been asked to fund this so has not evaluated it. That"s really rather reassuring isn"t it, because it implies that it is only being done in centres specialising in pancreatic surgery and with appropriate etc etc.?	Noted, thank you.
Individual respondent – carer	1 – recommendations	2	Consent, audit and clinical governance need some explanation for lay reader - what do they mean in common language. Also when should this procedure be used as opposed to standard laparotomy? This should be stated. Is this an alternative to laparotomy or preferred to laparotomy or an option instead of laparotomy? is it only an option in centres with the appropriate skills or something that all centres should be aiming towards? Should patients be opting to only have surgery in centres performing laparoscopy?	This is explained in the 'Understanding NICE guidance' document. Section 2.1.1 lists the indications for which the procedure is appropriate. Section 1.2 states that the procedure should only be performed in centres specialising in pancreatic surgery and with appropriate expertise in laparoscopic techniques.

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Individual respondent – carer	2.1 – Indications	3	This section is not clear. It says nothing about how. In terms of when the description in the overview is much clearer. You have no clear statement about which indications it is to be used for. You just have a description of different diseases. Need a clear statement - this procedure is indicated for the following diseases: Neuroendocrine and cystic tumours of the pancreas, chronic pancreatitis, pancreatic pseudocysts. You also need to clearly state whether the procedure is recommended(indicated) for both malignant and benign neuroendocrine and cystic tumours. what is the point of 2.1.3. The heading in the overview is clearer ie Current treatment and alternatives. This heading should be added to 2.1.3. I think you need an extra sentence to say something like "where surgery is needed for these diseases this procedure".. should or can be used and under what circumstances.	The Committee changed the wording of section 2.1.1 to read: lLaparoscopic pancreatectomy may be used for the treatment of a number of different conditions. • Pancreatic neuroendocrine tumours (most commonly insulinoma) and cystic tumours (benign or malignant) are usually treated surgically. Small benign insulinomas can be removed by enucleation. Larger tumours in the body or tail of the pancreas or close to the pancreatic duct are conventionally removed by open distal pancreatectomy. Chemotherapy may also be used to treat some malignant tumours. • Chronic pancreatitis refers to long-term inflammation of the pancreas, which eventually causes irreversible damage to the tissue. Treatment includes medication such as enzyme supplements and analgesics, and avoiding alcohol consumption. Surgery may occasionally be necessary, including for patients with chronic pancreatitis complicated by pseudocyst formation. • Andenocarcinoma seldom presents as a tumour in the tail of the pancreas but may occasionally be found on histological examination following resection of a space-occupying lesion.’

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Individual respondent – carer	2.2 – Outline of the procedure	4	again the overview is clearer. Why have you missed out the bit about preimaging and insufflation by carbon dioxide? The latter part is important as it has special effects that need careful explanation to the patient. My husband had a laparoscopy for surgical investigation (but no actual surgery) for pancreatic adenocarcinoma and the guidance clearly explained that this would be done and how it could lead to referred pain in the shoulder etc as the carbon dioxide dispersed. I suggest replacing this with the description in the overview. Why have you removed the explanation of what enucleation means - again add in the explantion in the overview - ie shelling out without removing any of the pancreas.	The Committee changed the wording of section 2.2.1 to read: 'The abdomen is insufflated with inert gas and a number of small incisions are made to provide access for the laparoscope and surgical instruments.'

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Individual respondent – carer	2.3 – Efficacy	5	The overview mentions that specialists commented on long term recurrence and survival. This is not mentioned here. Is that due to lack of published evidence? There is an additional benefit to patients frightened of major surgery so an impact on mental health. I had one patient comment on this that she wished laparoscopy had been available for her as she was so frightened of the open surgery. Impact on quality of life and social functioning - presumably through less scarring which may be of especial importance to women. Is there any impact on long term pain? With full Whipple's surgery I know that there are major longterm problems with hernias which are a great cause of concern to patients and something which cannot be resolved due to the extent of the surgery. Presumably the same applies to distal pancreatectomy and with laparoscopic surgery the risk/problems with hernias may possibly be less? Are there benefits in terms of risk of infection in wounds and time for wound healing etc?)in response to my queries above one of the surgeons on our advisory board has said "hernias, pain and short term recovery are the potential advantages and scarring, particularly for small neuroendocrines".	Section 2.3.4 states that there is a lack of data on long-term follow-up. Thank you. There were no randomised controlled trials identified that compared laparoscopic surgery with open surgery. The outcomes presented in the guidance are those that have been published.

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Individual respondent – carer	2.4 – Safety	6	as mentioned above the short-term effect of the carbon dioxide insufflation isn't mentioned (surgeon from advisory board's response to my comments are: "and other sources of referred pain such as due to diaphragmatic stretch / irritation as much as gas and the fact that its CO2 doesnt really matter (other gases also result in some discomfort from time to time") - not a major problem but just something that the patient needs to be aware of and understand. The overall direct side-effects of the surgery by this method may be less than from open surgery and this is not touched on in the description. It only mentions times for recovery but not what the patient has to deal with in the 2 different procedures eg wound healing, pain, risk of MRSA , number of tubes, drains etc	Thank you. The guidance is not intended to inform patients of every possible effect of the procedure. This should be explained during the patient consent process. There were no randomised controlled trials identified that compared laparoscopic surgery with open surgery.
Individual respondent – carer	General comments	7	Procedure should be available as an option to the patients who may benefit.	Thank you, your comment has been noted.

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Individual respondent – carer	General comments	8	1. Presumably if there was any possibility of the tumour being adenocarcinoma (as was believed in my husband's case), this procedure would not be recommended because of the possibility of contamination/inadequate margins. 2. What about malignant neuroendocrine tumours? Is this procedure recommended, and are there greater risks of contamination and therefore spread (not merely recurrence) of the disease? Are there any statistics comparing rates of metastatic disease after the two procedures? And what is the rate of recurrence after open surgery as compared with 5.7% at 27 months for the laparoscopic procedure? 3. How small would a tumour have to be to be suitable for this procedure? 4. If a splenectomy has to be performed at the same time, do the risks of haemorrhage increase significantly compared to those in the open procedure? 5. What are the mean rates of reoperation for complications and pancreatic fistula in the open surgery? Are they higher, lower or similar?	1. The guidance relates only to the indications stated (pancreatic neuroendocrine and cystic tumours and chronic pancreatitis). 2. Section 2.1.1 states that the tumours may be benign or malignant. There were no randomised controlled trials identified that compared laparoscopic surgery with open surgery. 3. The guidance does not state that this procedure is only suitable for small tumours. The respondent's other questions are beyond the scope of the guidance.

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Clinician member of Pancreatic Cancer UK's Medical and Scientific Advisory Board	General comments	9	Laparoscopy should be an option that is available but only in expert centres. It is likely in practice to only be used in functioning neuroendocrine tumours as non-functioning ones tend to be too large for laparoscopic surgery once found due to lack of symptoms. Type of surgery should be clinician preference rather than patient preference as a patient say wanting laparoscopic surgery may bias a surgeon that way when clinically the better results eg in terms of removing all tumour may be to use open surgery rather than laparoscopic.	Thank you, your comment has been noted.