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Title:
Evaluation of palliative treatments in unresectable pancreatic cancer

Date:
2021-05-01

Citation:
Choi, C. C. M., Choi, J., Houli, N., Smith, M., Usatoff, V., Lipton, L. & Chan, S. (2021). Evaluation of palliative treatments in unresectable pancreatic cancer. ANZ Journal of Surgery, 91 (5), pp.915-920. https://doi.org/10.1111/ans.16669.

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Full title: Evaluation of palliative treatments in unresectable pancreatic cancer

Running Head: Unresectable pancreas tumour palliation

Type of manuscript: Original Article

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Number of figures: 2

Number of table: 1

Number of supporting information: 0

Word count (abstract): 247

Word count (text): 4000 (excluding acknowledgements, disclosure and figure legends)

Keywords: Pancreatic Neoplasms, Palliative care, Surgical Procedures, Operative, Exocrine Pancreatic Insufficiency, Diabetes Mellitus

Disclosure: The authors declare no conflict of interests.

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Abstract

Background: Pancreatic ductal adenocarcinoma (PDAC) presents as unresectable disease in 80% of patients. Limited Australian data exists regarding management and outcome of palliative management for PDAC. This study aims to: (1) identify patients with PDAC being managed with palliative intent; (2) assess the type of palliative management being used.

Methods: A prospectively maintained pancreatic database at Western Health (2015 – 2017) was used to identify patient demographics; stage and multidisciplinary decision regarding resectability and operative interventions; palliative care; use of chemotherapy, radiotherapy and; management of exocrine and endocrine insufficiency. Data on chemotherapy use, number of hospital admissions, emergency department attendances and intensive care unit admissions 30 days prior to death were recorded.

Results: One-hundred eleven patients had diagnosis of PDAC, 15% with locally advanced and 45% with metastatic PDAC. Amongst the locally advanced and metastatic PDAC, 48% received biliary stent insertions, 93% had palliative care referral, 45% received palliative chemotherapy and 10% received radiotherapy. Dietitian referral occurred in 79% and 36% were prescribed with a pancreatic enzyme replacement therapy. Diabetes mellitus was present in 52% of which 31% was new onset. Within 30 days prior to death, 11% patients received palliative chemotherapy, 32% were hospitalised and 11% visited an emergency department more than once. Sixty-five percent died in hospital.

Conclusion: A high proportion of patients diagnosed with locally advanced and metastatic PDAC received palliative care referrals and appropriate level of end-of-life care. Further prospective studies are necessary, examining the management and impacts of pancreatic insufficiency in this group.

Introduction

Pancreatic ductal adenocarcinoma (PDAC) presents as unresectable disease in 80% of patients and represents a major cancer burden in Australia, estimated to be the fifth most common cause of mortality.[1, 2]

There are few studies examining the patterns of treatments for palliative PDAC with the literature often focusing on evaluating resectable or borderline resectable PDAC.[1, 3, 4]

In this context, the current study presents an opportunity to evaluate patterns of management for advanced PDAC in local setting. The institutional hepatopancreatobiliary multidisciplinary team not only discussed patients with resectable, borderline resectable pancreatic cancer, but also those with locally advanced pancreatic cancer (LAPC) and metastatic pancreatic cancer (MPC).[5]

This study aimed to identify PDAC patients with palliative treatment intent, their palliative management and their outcomes.

Methods

Database and study design

A retrospective study was applied using a prospectively managed REDCap pancreatic electronic database hosted at The University of Melbourne, between January 1, 2015 and December 31, 2017. The database includes all PDAC patients referred to the Western Health multidisciplinary team. Ethics approval was obtained from the institutional ethics committee.

Patient selection

All patients with radiological and/or histological diagnosis of PDAC and aged >18 years were included. LAPC was defined if greater than 180° superior mesenteric artery or coeliac artery encasement, and major venous involvement with un-reconstructable superior mesenteric and portal vein were demonstrated.[5] MPC was defined as distant metastasis demonstrated on staging computed tomography, magnetic resonance imaging or positron emission tomography. Figure 1 shows the exclusion criteria.

Data collection and study parameters

Study parameters included gender, age at diagnosis, initial Eastern Cooperative Oncology Group Performance Status (ECOG PS), initial Carbohydrate antigen 19-9 (CA19-9) and Carcinoembryonic antigen (CEA) level, tumour site, stage and sites of metastases.

Palliative treatments

The treatment approach was classified as 'palliative' for LAPC and MPC.[5] Documented invasive procedures included endoscopic retrograde cholangiopancreatography (ERCP) and percutaneous transhepatic cholangiography (PTC) for biliary stenting, bypass surgery, laparotomy, laparoscopy and gastroscopy for duodenal stenting.

Management of pancreatic exocrine insufficiency (PEI) and endocrine insufficiency were reviewed. Diagnosis of PEI was based on steatorrhoea and weight loss. Diabetes mellitus (DM) was defined if haemoglobin A1c (HbA1c) ≥6.5%, fasting blood glucose ≥7.0 mmol/L, random blood glucose ≥11.1 mmol/L or if on antidiabetic medication. DM was classified as either (1) long standing or (2) new onset Type 3c diabetes mellitus (T3cDM) if diagnosed less than 2 years or at time of PDAC diagnosis.[6]

Referrals to hospital and community palliative care were noted. Neoadjuvant chemotherapy included FOLFIRINOX (folinic acid, fluorouracil, irinotecan and oxaliplatin) or gemcitabine plus paclitaxel NAB. Palliative chemotherapy and radiotherapy consisted of various regimens.

The aggressiveness of cancer care toward the end of life was assessed using the following indicators: (1) chemotherapy use, (2) number of hospital admission, (3) number of emergency department (ED) attendances and (4) intensive care unit (ICU) admissions within 30 days of death.[7] Mortality data were captured from the medical records.

Statistical analyses

Continuous variables were presented as median value with interquartile range (IQR) and categorical variables as frequency counts. Cases with missing data were omitted from denominators. Overall survival was calculated from the date of cancer diagnosis until death or last follow up. Kaplan-Meier graphs were used to deduce survival curves and log-rank test assessed difference of survival according to the resectability types. Statistical analysis was

performed with SPSS 25.0 (SPSS, Chicago, IL, USA). A *P*-value <0.05 was considered statistically significant.

Results

Of 631 pancreatic records, 110 PDAC were included and 67 LAPC and MPC were analysed (Fig. 1).

Baseline clinical characteristics

The median age of the LAPC and MPC was 69 years (IQR 62 – 77.5) (Table 1). PDAC was histologically confirmed in 85.1% (57/67).

Patterns of invasive interventions

Thirty-nine (58.2%) patients underwent invasive interventions. Four (10.3%) patients underwent diagnostic staging laparoscopy with one having laparoscopic gastrojejunal bypass. Laparotomies were performed in four (10.3%) patients; two cases of open gastrojejunostomy and the rest exploratory laparotomies. Thirty-two (82.1%) patients received 38 biliary stents; 84.4% (27/32) with ERCP and 15.6% (5/32) with PTC. ERCP was the first intervention of choice in 96.9% (31/32). Complications occurred in 22.2% (6/27); 83.3% (5/6) had ascending cholangitis with stent occlusion and 16.7% (1/6) undocumented complication. In this group, 18.6% (5/27) required reintervention. Forty percent (2/5) had complications from PTC, one ascending cholangitis with stent occlusion and one bile leakage from external drain. One patient required reintervention. Four (12.5%) patients were readmitted (3 ERCP and 1 PTC). There were no stent-related intraoperative complications.

Gastric outlet obstruction (GOO) was present in 10.4% (7/67). Two patients received metal duodenal stent insertion endoscopically and one percutaneously due to ascending cholangitis with stent occlusion.

Postoperative 30-day mortality rate was 19.4% (6/31); 2 with ERCP, 3 PTC and 1 with gastroscopy whereas 90-day mortality rate was 32.3% (10/31); 5 with ERCP, 3 PTC, 1 gastroscopy and 1 with laparoscopic bypass surgery.

Management of pancreatic exocrine insufficiency

Weight loss and steatorrhoea were present in 83.6% (56/67) and in 13.4% (9/67) respectively. Their median body mass index (BMI) at diagnosis was 25.2 kg/m^2 (IQR 21.9 – 29.1), a 13.3% (IQR 7.4 – 17.3) reduction from median pre-illness state BMI (29.4 kg/m^2, IQR 25.2 – 32.2) (43/67 documented). At diagnosis, 50% (28/56) had BMI reduction greater than 10% in less than 6 months. Fifty-three (79.1%) were referred to dietitians. Pancreatic enzyme replacement therapy (PERT) was prescribed for 24 patients with 70.8% (17/24) given at time of diagnosis. Among them, 62.5% (15/24) only had weight loss and 33.3% (8/24) had steatorrhoea as well. Steatorrhoea persisted in 12.5% (3/24). Pancrelipase dose varied from 10,000 to 50,000 units with each meal. The rest 54.7% (29/53) received dietary modification only.

Management of pancreatic endocrine insufficiency

Diabetes mellitus (DM) was present in 52.2% (35/67). Of those, 68.6% (24/35) had long-standing Type 2 diabetes mellitus (T2DM) and 31.4% (11/35) had new onset, T3cDM, peri-cancer diagnosis. Twenty-seven percent (3/11) of T3cDM were identified following PDAC diagnosis (50/67 assessed). A small number (9/35) was referred to diabetic educators. T2DM worsened in 37.5% (9/24) with disease progression, requiring switch to insulin therapy from diabetic diet or oral hypoglycaemic agents. Seventy-three percent (8/11) of T3cDM newly commenced on oral hypoglycaemic agent or insulin. PEI was suspected in 42.9% (15/35) of which 73.3% (11/15) were long standing DM and 26.7% (4/15) were new onset DM.

Patterns of oncological treatments

Palliative chemotherapy was administered in 30 (44.8%) patients, in 64.7% (11/17) of LAPC and 38% (19/50) of MPC patients. Their median age was 67 (IQR 63.3 – 71) years. The rest 37 (55.2%) patients declined or had poor ECOG performance status for chemotherapy. Three patients with LAPC for neoadjuvant chemotherapy had disease progression. As first line chemotherapy, 23 (76.7%) were given gemcitabine plus nab-paclitaxel, 5 (16.7%) enrolled in YOSEMITE trial[8] and 2 (6.7%) were given unknown regimen at external centres. Eighteen (60%), 8 (26.7%), 2 (6.7%) and 2 (6.7%) received first, second, third and fourth line of chemotherapy respectively. Ten percent (3/30) received concurrent chemoradiotherapy as second or third line. Radiotherapy was administered in 7 (10.4%).

Patterns of end-of-life care

Sixty-two (92.5%) and 50 (74.6%) patients respectively had hospital and community palliative care referrals. Eighteen (26.9%) were followed up by outpatient symptom management clinic. Seven (10.4%) and two (3.0%) respectively were referred to hospital-in-the-home and hospice service. The median number of inpatient palliative care visit was five (IQR 1 – 10). Sixty (89.6%) patients received opioid analgesics. Among them, 1 (1.7%) patient had endoscopic ultrasound guided coeliac plexus neurolysis and 7 (11.7%) computed tomography guided coeliac plexus block. Fifty-seven (85.1%) palliative patients had died by last follow up (May 2019). Six (11%) received chemotherapy in last month of life. One (16.7%) was on first line, 4 (66.7%) on second line and 1 (16.7%) on fourth line of chemotherapy during this period. Within 30 days of death, six (11%) patients had multiple ED attendances and 18 (31.6%) had multiple hospital admissions. In this period, the median number of ED attendance was two (IQR 2 – 2.8). The median number of hospitalisation and inpatient days were 2 (IQR 2 – 3) and 12 (IQR 4.3 – 23.8) respectively. There were no ICU admissions during this period. More than half (32/57) of palliative patients did not have chemotherapy, multiple ED visit, multiple hospitalisations and ICU admissions within 30 days of death.

Survival and place of death

The median survival of patients with LAPC and MPC was 6.3 months, significantly shorter than 17.6 months and 23.6 months of the borderline resectable and resectable groups (P = 0.0001, Fig. 2A). The median survival was 16.5 months and 5.0 months for LAPC and MPC respectively (P = 0.004, Fig. 2B).

Death in hospital accounted for 64.9% (37/57), of which 70.3% (26/37) in palliative care unit, 10.8% (4/37) in oncology unit, 2.7% (1/37) at other hospital and 16.2% (6/37) in an acute hospital. Of 35.1% (20/57) who died in community, 70% (14/20) was from community palliative care, 15% (3/20) from residential care and 15% (3/20) from home. Forty-nine percent (22/45) was transferred from community to inpatient palliative care.

Discussion

There is a paucity of Australian research evaluating broad patterns of palliative care and management, distinguishing between LAPC and MPC.[9] This study presents local Australian data utilising the institutional pancreatic database.

A high proportion of the cohort received palliative care referrals and appropriate level of end-of-life care in the final month of life; only 11% had multiple ED visits and 32% had hospitalisations, markedly lower than the US or Canadian studies.[10-12] The ICU admission rate was similar to an Australian study whereas Sheffield reported a rate between 14.8% and 17.7%.[9, 11] Although chemotherapy use was lower, the number of lines were comparable to an European study.[13] This study highlights that palliative management in community could reduce ED visits and hospital admissions, and early palliative care referral has been shown to reduce inappropriate end-of-life care within 30 days of life.[9, 10] This study shows that a small number (10.5%) die in the community setting.[9]

This study shows a lack of clear guideline for diagnosis and management of pancreatic exocrine insufficiency (PEI) for palliative PDAC. PEI is a clinical diagnosis in this study, not routinely based on tests such as faecal elastase-1 (FE-1) or secretin. Weight loss in PDAC, however, is often multifactorial. While steatorrhoea is an uncommon finding, an Italian study has shown that 50% of LAPC or MPC had moderate to extremely reduced exocrine function based on FE-1.[14] However, a more recent pilot study shows a poor diagnostic value of FE-1 in detection of PEI.[15] Despite a high rate of dietitian referral, only a minority received PERT and dose often lower than the guideline recommendations.[5, 16] Further research in patterns of diagnosis, nutritional evaluation and management is critical to identify opportunities to reduce burdens of PEI.

Clinical gaps in diagnosis and management of endocrine insufficiency are demonstrated in this study. The prevalence of DM has been reported between 40% and 75% and new onset DM in 52% of all diabetic PDAC patients.[6, 17, 18] Despite these findings, this study reveals that only 75% of PDAC was assessed for DM at diagnosis. Furthermore, distinguishing T3cDM from other DM types becomes an issue. It has been suggested that nearly half of T3cDM patients had been misdiagnosed as either Type 1 diabetes mellitus or T2DM.[19] A proposed diagnostic criteria for T3cDM are based on criteria of (1) presence of PEI (based on FE-1 or direct function test), (2) pathological pancreatic imaging and (3) absence of type 1

DM associated autoimmune markers or based on features including age over 65 years, recent weight loss of >2 kg, lack of family history of DM.[20, 21] 31% (11/35) of diabetic patients had new onset DM, but 37.5% (9/24) of T2DM also worsened post cancer diagnosis. PEI was suspected in 45.8% (11/24) of T2DM. A better diagnostic and management for DM of PDAC is crucial.

The study population demonstrates a trend away from surgery towards endoscopic management for biliary obstruction and GOO.[5, 22] ERCP was the procedure of choice for biliary stenting and PTC was utilised when proximal biliary stricture was present. Endoscopic duodenal stenting is preferable to gastrojejunostomy and following chemotherapy.[22, 23] Fifty-seven percent (4/7) of GOO cases received invasive interventions including operative gastroenterostomy. The 30-day and 90-day mortality (19.4% and 32.3% respectively) remain high despite low rates of interventions.

Similar to an Australian study, only 44.8% of the cohort received palliative chemotherapy.[24] Only a minority of them received FOLFIRINOX. Only 10% of patients received radiotherapy, similar to 8% a population-based Australian study although the LAP07 trial has shown that it is associated with greater chemotherapy-free interval and local control.[25, 26]

The weakness of the study is its retrospective nature of prospectively maintained pancreatic database in a single institution with a small sample size. Although all patients with diagnosis of PDAC referred to hepatopancreatobiliary unit or oncology are included in the database, there is a potential to omit patients. To our knowledge, this represents one of the largest Australian evaluation in management of pancreatic exocrine and endocrine insufficiency in a cohort with palliative PDAC. The patterns of care may have changed since the data were collected, however, the management of palliative PDAC is consistent with current evidence-based and high-quality care. A prospective study on cost effectiveness of palliative treatments will also be beneficial to further improve outcomes and reduce rising costs of treatments.

In conclusion, this study presents comprehensive data on palliative patients in real-life practice. As pancreatic surgeons, we provide curative surgical interventions in a small proportion of patients. Unresectable PDAC patients require multidisciplinary approach in

management of their clinical issues such as palliative chemotherapy, pain, nutritional support, exocrine and endocrine insufficiency. We should attend to holistic care of pancreatic cancer patients and advocate for excellence in their palliative care.

Acknowledgement

We would like to acknowledge the important contribution from the Western Health Upper Gastrointestinal and Hepatopancreatobiliary Team.

Disclosure statement

The authors declare no conflict of interests.

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Figure legends

Figure 1: Flow diagram showing methods for inclusion and exclusion of pancreatic database records 2015 – 2017.

Figure 2: Kaplan-Meier overall survival analyses in the cohort of 110 PDAC patients at Western Health 2015 – 2017 stratified by (A) resectable, borderline resectable or palliative PDAC type (n = 110) and (B) presence of distant metastasis among palliative PDAC (n = 67).

Table

Characteristics	Palliative patients (n = 67)
Median Age (IQR)	69 (62 – 77.5)
Gender	
Male	34 (50.7%)
Female	33 (49.3%)
ECOG PS	
0	5 (7.5%)
1	33 (49.3%)
2	8 (11.9%)
3	7 (10.4%)
4	1 (1.5%)
Unknown	13 (19.4%)
Median Tumour Diameter (mm, IQR)	38 (28 – 46)
Tumour Location	
Head	34 (50.7%)
Uncinate	2 (3.0%)
Neck	2 (3.0%)
Body	4 (6.0%)
Tail	12 (17.9%)
Overlapping	13 (19.4%)
Tumour Extension	
Locally Advanced	17 (25.4%)
Metastatic	50 (74.6%)
Initial CA19-9 (U/ml, IQR)	
Overall	2570 (324 – 13500)
Locally Advanced	1012 (132 – 3735)
Metastatic	3670 (340 – 28800)
Initial CEA (ng/ml, IQR)	
Overall	5.3 (3.2 – 22.5)
Locally Advanced	4.2 (3.8 – 5.1)
Metastatic	6.7 (3.1 – 34)
Sites of Metastases	
Liver	38 (76%)
Lung	12 (24%)
Peritoneal/Omental	11 (22%)
Lymph Node	6 (12%)
Other	6 (12%)
Bilirubin > 50 umol/L at diagnosis	23 (34%)

Table 1. Demographics and disease characteristics of patients with locally advanced pancreatic cancer and metastatic pancreatic cancer (n = 67).

Figure 1

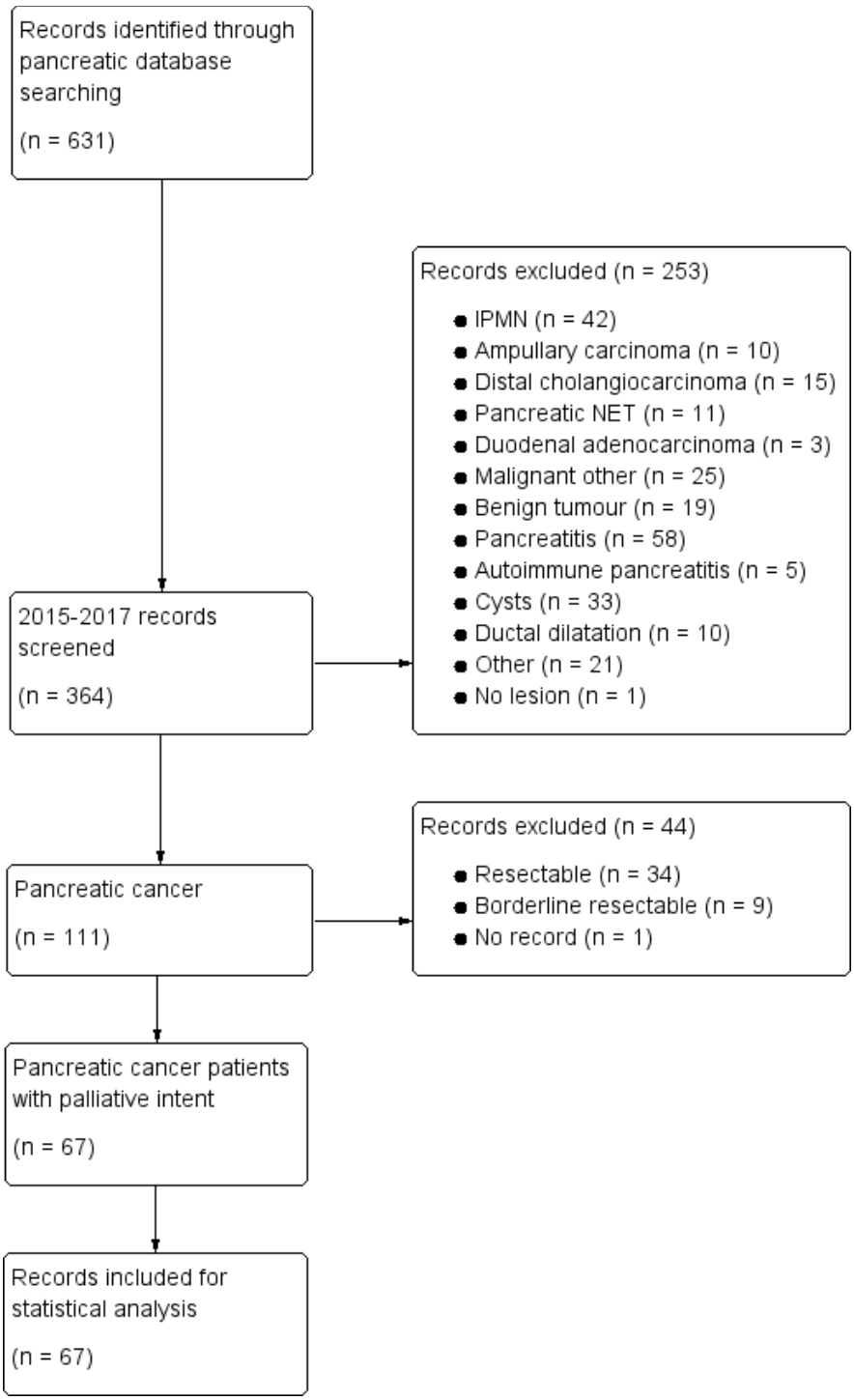

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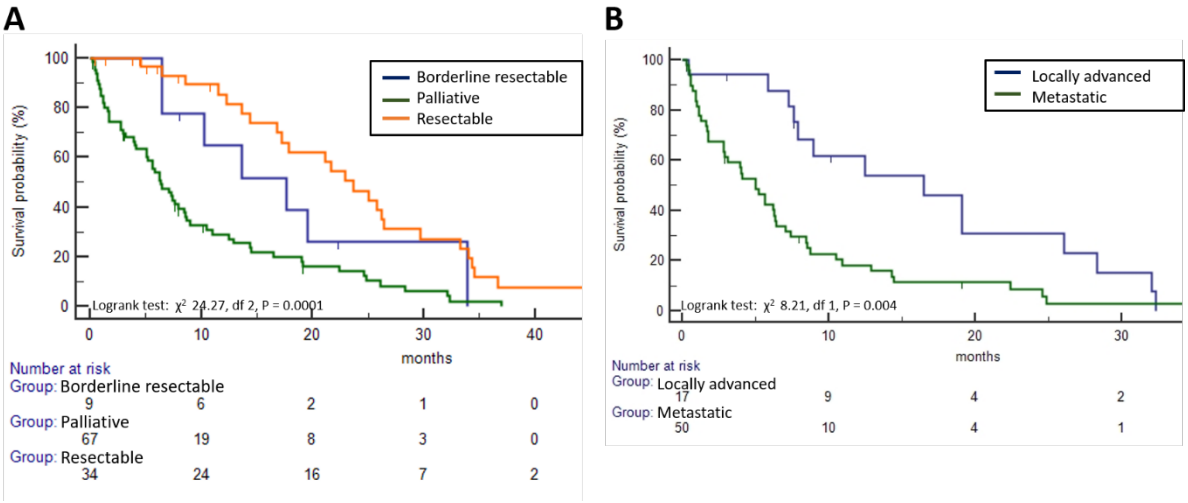
Figure 2



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