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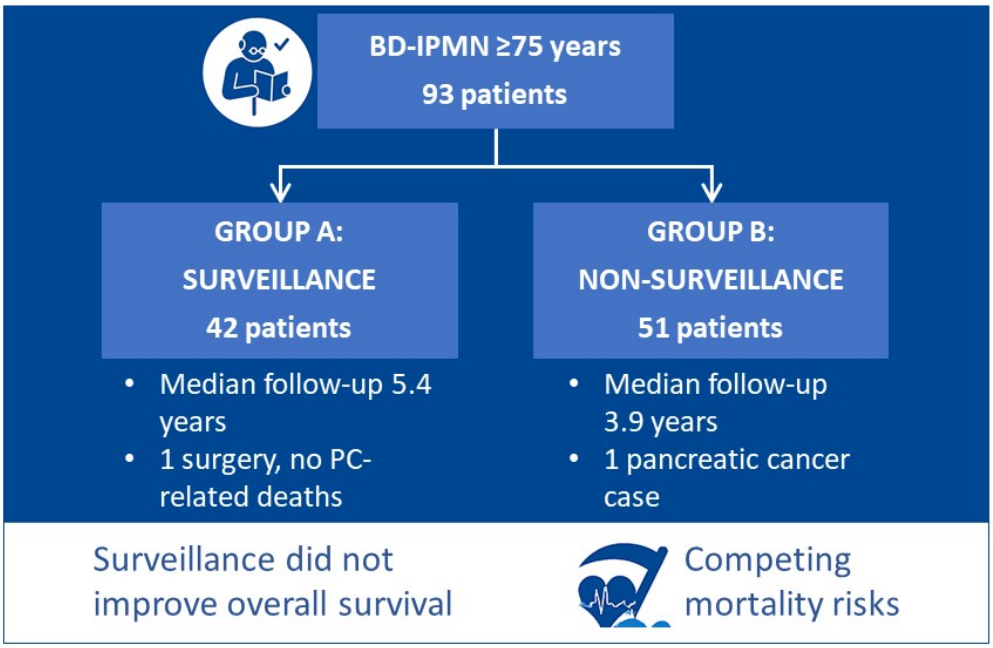
Surveillance of BD-IPMN in Patients Aged ≥75: Is It Justified?



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LIST OF ABBREVIATIONS

BD-IPMN: Branch-duct Intraductal Papillary Mucinous Neoplasms

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CPLs: Cystic Pancreatic Lesions

CT: Computed Tomography scan

MRI: Magnetic Resonance Imaging

MRCP: Magnetic Resonance Cholangiopancreatography

EUS: Endoscopic Ultrasound

ACCI: Age-adjusted Charlson Comorbidity Index

SCA: Serous Cystadenoma

MCN: Mucinous Cystic Neoplasm

MPD: Main Pancreatic Duct

IAP: International Association of Pancreatology

FNA: Fine Needle Aspiration

PDAC: Pancreatic Ductal Adenocarcinoma

HRS: High-risk Stigmata

SD: Standard Deviation

IQR: Interquartile Range

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ABSTRACT

Introduction: Incidental cystic pancreatic lesions are increasingly detected in the aging population, with branch-duct intraductal papillary mucinous neoplasms (BD-IPMNs) being the most common. This study aimed to evaluate the benefits of implementing a surveillance program in patients diagnosed with presumed BD-IPMN at the age of 75 years or older.

Methods: A retrospective analysis was conducted using a prospective registry of patients diagnosed incidentally with presumed BD-IPMN at ≥75 years of age. Patients were categorized into two groups: Group A, who underwent clinical and imaging follow-up, and Group B, who received no surveillance. Clinical records were reviewed to assess pancreatic cancer incidence, overall survival, and mortality.

Results: Among 434 patients with BD-IPMN, 93 met inclusion criteria (42 in Group A; 51 in Group B). The mean age was 77 years in Group A and 79.2 years in Group B (p=0.016). The mean cyst size was 15.6 mm in Group A and 14.6 mm in Group B (p=0.56). No cases of pancreatic cancer were identified in Group A, while one case occurred in Group B (p=1.0). Five patients died in each group (p=1.0). Overall survival was comparable between groups (HR 0.8; 95% CI: 0.22–2.94; p=0.74).

Conclusions: Presumed incidental BD-IPMNs diagnosed at ≥75 years of age rarely progress to pancreatic cancer. In patients with cysts <2 cm and without high-risk features, surveillance does not appear to confer a survival benefit and may therefore be unnecessary.

Keywords: Intraductal papillary mucinous neoplasm. Survival. Follow-up. Pancreatic cancer.

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INTRODUCTION

The use of cross-sectional imaging has increased significantly in recent decades, leading to the frequent incidental detection of cystic pancreatic lesions (CPLs), particularly in the aging population (1). Among these, mucinous lesions—especially intraductal papillary mucinous neoplasms (IPMNs)—are the most commonly identified (2).

Surgical resection is generally recommended for patients with high-risk morphological features, given the malignant potential of these lesions. In the absence of such features, surveillance is typically advised (3,4). Over the past decade, several international guidelines have sought to optimize criteria for selecting patients for surgical resection versus those eligible for imaging-based surveillance programs (5–8). However, there remains uncertainty regarding the age at which surveillance ceases to provide meaningful clinical benefit.

In 2018, the American College of Gastroenterology (ACG) suggested that follow-up may be discontinued at age 75 (9). Yet, current guidelines provide limited direction on how to manage patients who are newly diagnosed with incidental CPLs at or beyond this age. In general, surveillance is discouraged in patients who, due to age or comorbidities, are considered unfit for pancreatectomy. However, improvements in surgical techniques and increasing life expectancy have complicated the assessment of surgical fitness in older adults. As a result, many clinicians are reluctant to use age alone as a criterion for excluding patients from surveillance, despite the significant burden this places on healthcare systems. Additionally, discontinuing follow-up may negatively affect patients' physical and psychological well-being (10). Moreover, competing risks of mortality warrant careful consideration in clinical decision-making.

The aim of this study was to evaluate the impact of a surveillance program initiated after the incidental diagnosis of a presumed branch-duct IPMN (BD-IPMN) in patients aged 75 years or older, specifically regarding the development of pancreatic cancer and overall mortality.

METHODS

Study Design

A retrospective analysis was conducted using a prospective registry of patients with cystic pancreatic lesions (CPLs). The study included individuals diagnosed with an incidental CPL between 2012 and 2024. Only patients with a presumptive diagnosis of a BD-IPMN were included in the final analysis. The study protocol was approved by the Regional Clinical Research Ethics Committee (reference 2023/459). The study design, data collection, and analysis adhered to the STROBE guidelines for observational research (11).

Participants and Study Groups

Eligible patients were ≥75 years of age at the time of an incidental CPL diagnosis, confirmed by imaging techniques such as computed tomography (CT), magnetic resonance imaging (MRI), magnetic resonance cholangiopancreatography (MRCP), or endoscopic ultrasound (EUS), with a presumptive diagnosis of BD-IPMN.

Exclusion criteria were as follows:

- Diagnosis of CPL prior to age 75.
- Symptomatic CPL (e.g., acute pancreatitis without another identifiable cause, obstructive jaundice due to cyst compression, or feeding intolerance from cyst size).
- Non-BD-IPMN CPLs.
- Upfront surgical resection due to high-risk stigmata (HRS).
- Clearly unfit for surgery (e.g., severe portal hypertension or significant cardiopulmonary, renal, or neurological comorbidities)

All eligible patients were offered enrollment in an imaging-based surveillance program. As a general departmental policy, patients with an Age-adjusted Charlson Comorbidity Index (ACCI) >3 were typically not considered for surveillance. However, the ACCI was applied as an auxiliary tool rather than a strict exclusion criterion, with final decisions

individualized based on cyst morphology, patient age, comorbidities, functional status, clinical judgment, and patient preference. A thorough explanation of the risks and benefits of surveillance was provided, focusing on the malignancy risk and life expectancy. Ultimately, the patient's preference guided inclusion in the follow-up program after consultation with their physician.

Patients were categorized into two groups:

- Group A: Patients included in a clinical and imaging-based surveillance program.
- Group B: Patients who did not undergo surveillance.

Variables and Definitions

Demographic, clinical, and morphologic data were prospectively collected. For Group A, data were obtained during follow-up in the pancreas unit. For Group B, data were extracted from electronic medical records until the end of the study period or the patient's death. Follow-up duration was calculated from the initial CPL diagnosis to death or study end. For Group A, surveillance discontinuation was followed by a final review of medical records.

An incidental CPL was defined as a cyst detected on imaging performed for unrelated clinical reasons. The presumptive diagnosis was based on clinical and imaging criteria. Possible diagnoses included BD-IPMN, serous cystadenoma (SCA), mucinous cystic neoplasm (MCN), cystic pancreatic neuroendocrine tumors, or indeterminate lesions.

A BD-IPMN diagnosis required the presence of one or more dilated branch ducts communicating with a nondilated main pancreatic duct (≤5 mm), confirmed via high-resolution imaging and/or EUS, often in the context of multifocal cysts. A main duct (MD)-IPMN was defined by uniform dilation (>5 mm) of the entire main pancreatic duct. SCA diagnosis was based on the characteristic microcystic "honeycomb" pattern or, in macrocystic variants, compatible fluid analysis (normal glucose, low carcinoembryonic antigen [CEA]). In cases with multiple lesions, the largest cyst was

analyzed.

During follow-up, MRI/MRCP was routinely performed in patients with incidental CPLs without high-risk features, at intervals consistent with international guidelines (5–7). EUS with or without fine needle aspiration (FNA) was reserved for cysts with high-risk features or diagnostic uncertainty. High-risk features were defined according to the Fukuoka guidelines (5).

Endpoints

The primary endpoint was the development of pancreatic cancer or the need for pancreatic surgery. Pancreatic cancer was defined as IPMN-associated invasive carcinoma or IPMN with concomitant pancreatic ductal adenocarcinoma (PDAC), confirmed by cytology, histology, or resected specimen analysis. In patients without histological confirmation, malignancy was presumed if distant metastases were present in the absence of another primary tumor. Pancreatic surgery was defined as any pancreatectomy performed during follow-up, whether due to progression of the BD-IPMN or unrelated causes (e.g., a concomitant PDAC). Surgery was indicated when HRS developed or symptoms emerged.

The secondary endpoint was overall survival, calculated from the date of CPL diagnosis to death or the end of the study. Overall and cause-specific mortality (related or unrelated to pancreatic cancer) were recorded. Cause of death was determined using patient death records.

Statistical Analysis

Continuous variables are presented as mean ± standard deviation (SD) or median and interquartile range (IQR), as appropriate, and were compared using the Student's t-test or Mann-Whitney U test. Categorical variables are expressed as percentages and analyzed using the Chi-square test or Fisher's exact test. Survival analysis was

performed using the Kaplan-Meier method. Statistical analyses were conducted using STATA software.

RESULTS

Between January 2012 and October 2024, a total of 434 individuals were identified in the CPL registry. Of these, 93 met the inclusion criteria and were included in the final analysis. The patient flow diagram is presented in Figure 1, and baseline clinical characteristics are summarized in Table 1.

There were no significant differences between the groups in terms of demographic or clinical characteristics, except for age. Patients in Group B were significantly older than those in Group A. Most cysts in both groups were smaller than 3 cm at the time of diagnosis, and the majority of BD-IPMNs showed no high-risk features upon initial imaging.

The median follow-up was 5.4 years for Group A and 3.9 years for Group B. In Group A, the mean cyst size increased from 15.6 ± 8.7 mm at baseline to 16.8 ± 9.0 mm at the final imaging assessment ($p = 0.5$), corresponding to an annual growth rate of less than 2.5 mm/year.

Development of Pancreatic Cancer and Surgical Interventions

During the study period, one patient (a male, age 84) in Group B developed pancreatic cancer at the site of a previously identified incidental BD-IPMN. Surveillance had not been initiated due to significant comorbidities. The malignancy was diagnosed at stage IV, and the patient died four years after the initial cyst diagnosis.

In Group A, one patient underwent pancreatic surgery, three years after surveillance had been discontinued, due to the development of ampullary cancer. This patient,

aged 80 at the time, had elected to stop follow-up based on age and personal preference. A pancreaticoduodenectomy was performed, and histopathological examination revealed a pT2N0M0 ampullary adenocarcinoma. The patient remains alive at the age of 88. No patients in Group B underwent pancreatic surgery during the follow-up period.

High-Risk and Worrisome Features

At baseline, six patients in Group A had features suggestive of increased risk: one exhibited a "high-risk stigmata" and five had "worrisome features" (three with one feature, two with two features). During surveillance, an additional five patients in Group A developed a single "worrisome feature"; however, none developed new "high-risk stigmata." In Group B, four patients had one "worrisome feature" at diagnosis (Table 2).

Mortality and Survival Analysis

During the study period, 10 patients (10.7%) died—five in each group (Table 3). Of these, only one death (Group B) was attributable to pancreatic cancer derived from a BD-IPMN. In Group A, causes of death included two cases of non-pancreatic malignancies (breast and urothelial cancer), two cases of cardiac arrest, and one case of renal failure with pneumonia. In Group B, causes included non-pancreatic malignancies (lung and hepatocellular carcinoma), heart failure, and complications following a hip fracture.

There was no statistically significant difference in overall survival between Group A and Group B. The Kaplan–Meier survival curve is shown in Figure 2.

DISCUSSION

This study found no evidence supporting the benefit of surveillance programs for patients aged 75 years or older diagnosed with presumed BD-IPMN. Only one patient developed pancreatic cancer during follow-up, and overall survival was similar regardless of whether patients underwent surveillance. Notably, most deaths in both groups were unrelated to pancreatic disease.

The increase in life expectancy over recent decades, combined with advancements in imaging technology, has led to the frequent detection of incidental CPLs, especially in the elderly population. This trend has created a significant burden on healthcare systems due to the resources needed for surveillance and management of these lesions. Prioritizing surveillance based on age and risk factors could help optimize resource allocation and patient care.

Cross-sectional imaging modalities, such as MRI and MRCP, have increased the detection rate of asymptomatic CPLs, with IPMNs being the most common(12). Because IPMNs carry malignant potential, efforts have historically focused on preventing progression to pancreatic cancer through surgical resection. However, evolving evidence has shifted the approach toward more conservative management, since the majority of incidental BD-IPMNs lack high-grade dysplasia or carcinoma upon surgical pathology(13,14). Most asymptomatic BD-IPMNs are small, stable, and carry a low risk of malignant transformation(14).

Despite improvements in imaging techniques, morphological characterization of CPLs remains imperfect(15,16). MRI is the preferred method for cyst evaluation, while EUS with or without fine-needle aspiration is reserved for cases requiring further diagnostic clarification(15). Due to diagnostic uncertainty and varying risks, multiple international guidelines have been published to aid clinical decision-making regarding surveillance versus surgery(5-9). Generally, surveillance is recommended for cysts without high-risk features, but the appropriate age to discontinue follow-up remains unclear.

Unlike many cancer screening programs, there is no consensus on a specific age threshold to stop surveillance for CPLs(17). The American College of Gastroenterology (ACG) guidelines are among the few to suggest reconsidering surveillance after age

75(8), but no firm recommendations exist for patients diagnosed with CPLs at or beyond this age. This uncertainty, combined with improvements in surgical safety and increasing life expectancy, complicates clinical decision-making.

Recent studies have introduced the concept of "trivial cysts," defined as BD-IPMNs without high-risk features that remain stable over at least five years(18). These cysts, particularly in patients older than 65, appear not to increase the risk of pancreatic malignancy significantly and may be candidates for surveillance discontinuation. An international multicenter study further suggested that the risk of developing pancreatic cancer after age 75 in such patients is comparable to that of the general population(19). Our findings are consistent with these observations and extend the conclusion by demonstrating that initiating surveillance in patients aged 75 or older with presumed BD-IPMN may not confer survival benefits.

Age and comorbidities are critical factors in clinical decisions for CPL management. Patients with higher comorbidity burdens face increased surgical risks and are more likely to die from causes unrelated to pancreatic cancer(20). In line with our results, Crippa et al. reported that in a large cohort of BD-IPMN patients without warning signs, only 1.6% developed pancreatic cancer, and age ≥75 years alongside an Age-Adjusted Charlson Comorbidity Index (ACCI) >3 independently predicted mortality unrelated to pancreatic malignancy(21). This emphasizes the importance of incorporating both age and comorbidities when considering surveillance strategies.

This study has several strengths. It is based on a large, prospectively maintained clinical registry from a specialized pancreas unit within a referral center, following standardized follow-up protocols. Additionally, the comprehensive regional electronic medical record system ensured robust data capture for patients not included in surveillance. However, there are limitations to consider. The retrospective design inherently introduces potential bias. The relatively small sample size, short follow-up period for some patients, and the low incidence of pancreatic cancer limit the statistical power of the analysis. The shorter follow-up may underestimate the risk of cancer development. Moreover, most patients had cysts smaller than 20 mm without high-risk features, which restricts the generalizability of the findings to larger or

higher-risk cysts. The heterogeneous duration of follow-up and varying criteria for discontinuing surveillance may also influence outcome interpretation. Finally, selection bias is likely, as clinicians often avoid surveillance in elderly patients considered unfit for surgery. This reflects real-world clinical practice rather than a randomized approach. Finally, the inclusion of patients with high comorbidity scores might have attenuated observable differences in survival outcomes between groups.

In conclusion, presumed incidental BD-IPMNs without high-risk features and smaller than 2 cm, diagnosed in patients aged 75 years or older, rarely progress to pancreatic cancer. Surveillance in this population may not provide survival benefit, as most mortality is unrelated to the cysts. Discontinuing or foregoing surveillance in these cases could reduce unnecessary medical interventions and healthcare burden while preserving patient quality of life. Large prospective longitudinal studies with longer and more uniform follow-up are warranted to confirm these results.

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Table 1. Baseline demographic, clinical, and cyst characteristics of patients diagnosed with presumed BD-IPMN at ≥75 years, stratified by surveillance status.

	Group A (n=42)	Group B (n=51)	p value
Age (years)			p=0.016*
Mean (sd)	77.0 (2.3)	79.2 (3.8)	
Range	75-82	75-90	
Gender			P=0.945
F	25 (59.5%)	30 (58.8%)	
M	17 (40.5%)	21 (41.2%)	
ACCI score			p=0.316
Mean (sd)	4.64 (1.36)	4.98 (1.78)	
Range	3-7	3-11	
ACCI score >3			p=0.828
No	9 (21.4%)	10 (19.6%)	
Yes	33 (78.6%)	41 (80.4%)	
Family history of PC (1st grade)			p=0.220
No	39 (92.9%)	50 (98.0%)	
Yes	3 (7.1%)	1 (2.0%)	
Gastrointestinal tumors			p=0.308
No	39 (92.9%)	44 (86.3%)	
Yes	3 (7.1%)	7 (13.7%)	
Other tumors			p=0.669
No	34 (80.9%)	43 (84.3%)	
Yes	8 (19.1%)	8 (15.7%)	
Cyst size (mm)			p=0.568
Mean (sd)	15.62 (8.70)	14.61 (8.25)	
Range	4-40	4-40	
Cyst size >30(mm)			p=0.812
No	40 (95.2%)	48 (94.1%)	
Yes	2 (4.8%)	3 (5.9%)	
First evaluation technique			p=0.005*[a]
CT-scan	6 (14.3%)	23 (45.1%)	
MRI /MRCP	5 (11.9%)	3 (5.9%)	
EUS	31 (73.8%)	25 (49.0%)	
Follow-up time (years)	**Surveillance**	**Clinical History Review**	p=0.005
Mean (sd)	5.44 (2.84)	3.95 (2.65)	
Range	1-12	1-12	

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	Group A (n=42)	Group B (n=51)	P value
EUS-FNA			p=0.505
No	36 (85.7%)	46 (90.2%)	
Yes	6 (14.3%)	5 (9.8%)	
Cyst location			p=0.557
Head	8 (19.1%)	9 (17.6%)	
Neck	6 (14.3%)	6 (11.8%)	
Body	3 (7.1%)	10 (19.6%)	
Tail	3 (7.1%)	3 (5.9%)	
Multifocal	22 (52.4%)	23 (45.1%)	
High-risk cyst feature			p=0.339[a]
No	36 (85.7%)	47 (92.2%)	
Yes	6 (14.3%)	4 (7.8%)	
Number of high-risk cyst features			p=0.377[a]
0	36 (85.7%)	46 (90.2%)	
1	4 (9.5%)	5 (9.8%)	
2	2 (4.8%)	0 (0%)	

Sd: standard deviation; CI: confidence interval; IQR: interquartile range; ACCI: Age-adjusted Charlson Comorbidity Index; PC: pancreatic cancer; EUS: endoscopic ultrasound; CT: computed tomography; MRI/MRCP: Magnetic resonance imaging/magnetic resonance cholangiopancreatography; FNA: Fine needle aspiration

a: Fisher test

b: Wilcoxon rank-sum test

***: statistically significant**

Table 2. High-risk stigmata and worrisome features at baseline and during follow-up in patients with presumed BD-IPMN aged ≥75 years.

High-risk cyst feature at diagnostic time	Group A n(%)	Grupo B n(%)	High-risk cyst feature during surveillance (group A)	N (%)
Enhancing mural nodules ≥5mm	1 (2.4%)		Size ≥30mm	1 (2.4%)
Size ≥30mm	2 (9.5%)	4 (7.8%)	Enhancing mural nodules <5mm	4 (9.5%)
Enhancing/thickened cystic wall	1 (2.4%)			
Main pancreatic duct ≥5mm <10mm	4 (9.5%)			

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Table 3. Outcomes of patients with presumed BD-IPMN aged ≥75 years according to surveillance status.

	Group A (n=42)		Group B (n=51)	p value
Size (mm)	**Diagnosis**	**Last control**		p=0.517
Mean (sd)	15.62 (8.70)	16.88 (9.05)		
Pancreatic cancer				
No	42 (100%)		50 (98.0%)	p=1.00
Yes	0		1 (2.0%)	
Mortality	5		5	p= 1.00[a]
PC-related	0		1 (2.0%)	
Non PC-related	5 (11.9%)		4 (7.8%)	
Time to death (years)				p=0.592[b]
Mean (sd)	3.6 (2.88)		3.00 (2.55)	
Overall survival (Kaplan Meier)	HR 0.80 IC95% (0.22-2.94)			P= 0.741

a: Fisher test

b: Wilcoxon rank-sum test

***: statistically significant**

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FIGURE LEGENDS

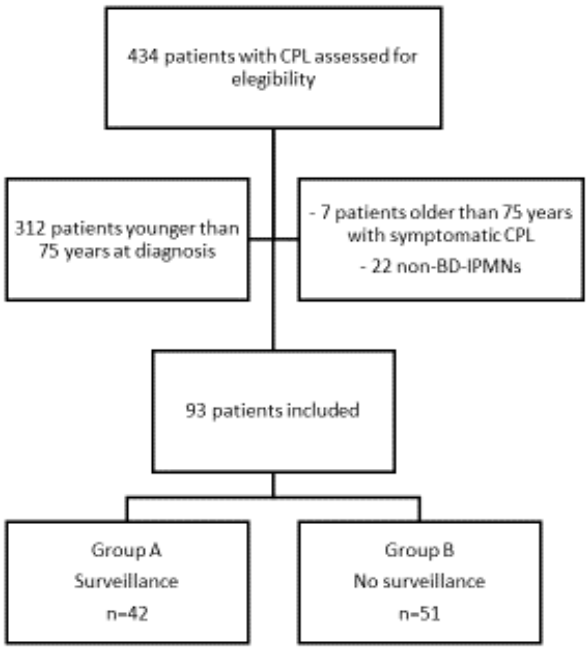

Figure 1. Flow chart illustrating patient selection and inclusion criteria for the study cohort.

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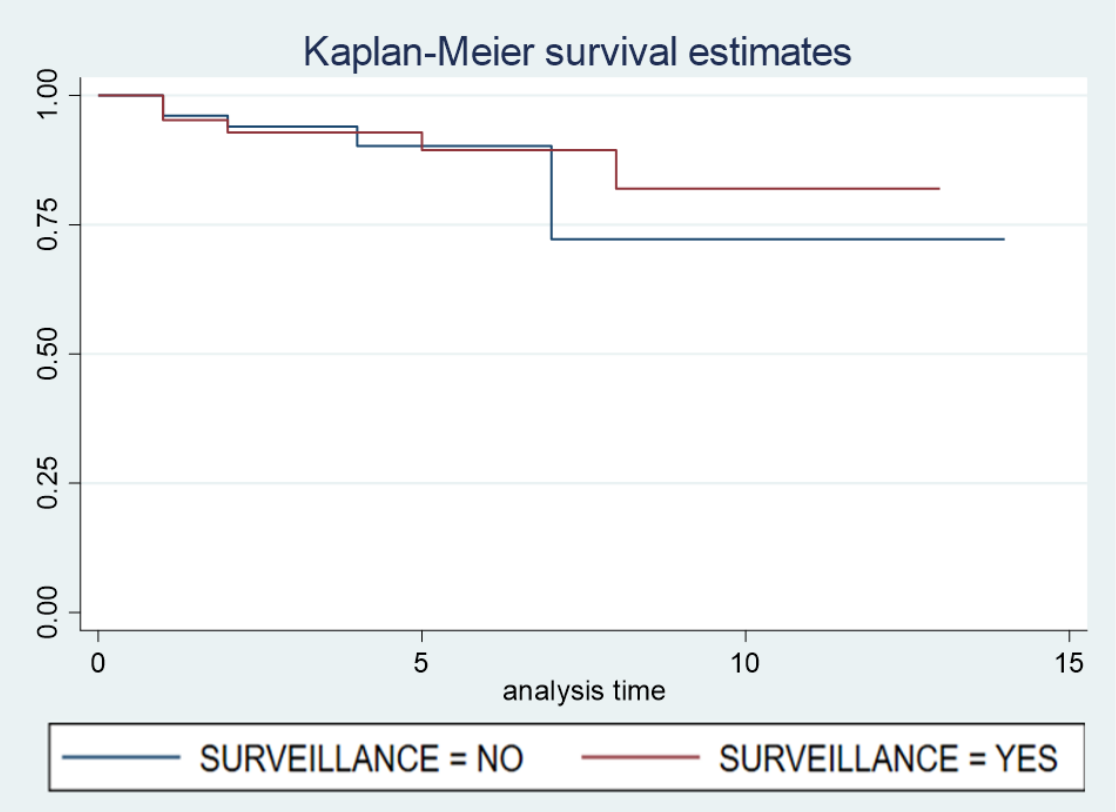

Figure 2. Kaplan-Meier survival curves comparing patients aged 75 years or older with presumed BD-IPMN, stratified by inclusion in or exclusion from a surveillance program.