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Benchmarking of minimally invasive distal pancreatectomy with splenectomy: European multicentre study

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Abstract

Background: Benchmarking is the process to used assess the best achievable results and compare outcomes with that standard. This study aimed to assess best achievable outcomes in minimally invasive distal pancreatectomy with splenectomy (MIDPS).

Methods: This retrospective study included consecutive patients undergoing MIDPS for any indication, between 2003 and 2019, in 31 European centres. Benchmarks of the main clinical outcomes were calculated according to the Achievable Benchmark of Care (ABC™) method. After identifying independent risk factors for severe morbidity and conversion, risk-adjusted ABCs were calculated for each subgroup of patients at risk.

Results: A total of 1595 patients were included. The ABC was 2.5 per cent for conversion and 8.4 per cent for severe morbidity. ABC values were 160 min for duration of operation time, 8.3 per cent for POPF, 1.8 per cent for reoperation, and 0 per cent for mortality. Multivariable analysis showed that conversion was associated with male sex (OR 1.48), BMI exceeding 30 kg/m² (OR 2.42), multivisceral resection (OR 3.04), and laparoscopy (OR 2.24). Increased risk of severe morbidity was associated with ASA fitness grade above II (OR 1.60), multivisceral resection (OR 1.88), and robotic approach (OR 1.87).

Conclusion: The benchmark values obtained using the ABC method represent optimal outcomes from best achievable care, including low complication rates and zero mortality. These benchmarks should be used to set standards to improve patient outcomes.

Introduction

Benchmarking is the process used to assess the best achievable results and compare outcomes with that standard¹. This concept is used broadly for quality improvement in the manufacturing industry and economy. Recently, healthcare facilities have also increasingly used quality measures to assess and enhance the quality of care, applying benchmarking to establish reference values for excellent care¹.

In the field of surgery, benchmarks represent the best achievable outcomes after a procedure, and can be used as a point of reference for assessing and comparing performance and quality standards^{1,2}. The standards should be set on the basis of the best achievable real-world postoperative outcomes, and the parameters used to define them should be reproducible, objective, and universal.

Recently, benchmarking has been applied in pancreatic^{3,4}, oesophageal⁵, and liver^{6–10} surgery, trying to set the standard to address. With regard to pancreatic surgery, benchmark values for clinically relevant outcomes have been set for pancreatoduodenectomy^{3,4}, but no study investigating distal pancreatectomy is currently available.

The aim of this study was to assess the best achievable outcomes in minimally invasive distal pancreatectomy with splenectomy (MIDPS), using a risk-adjusted benchmarking approach, in an unselected European patient population.

Methods

Study population and design

The study included patients enrolled by European centres performing at least 15 distal pancreatectomies annually, and participating in the European Consortium on Minimally Invasive Pancreatic Surgery (E-MIPS). The medical ethics review committee of Amsterdam UMC waived the need for informed consent owing to the retrospective observational study design. All participating centres received a database with the required parameters, including definitions. Data were then collected locally using prospective collected databases and gathered centrally by the study coordinators. Results were reported according to STROBE principles¹¹.

Inclusion and exclusion criteria

Consecutive patients, aged 18 years or above, were included after MIDPS for benign or malignant disease between 2003 and 2019.

Exclusion criteria were: patients scheduled for spleen-preserving distal pancreatectomy who underwent unplanned splenectomy; and patients with no details about the procedure performed and/or postoperative outcomes.

Aim and endpoints

The aim of this study was to assess the best achievable outcome in MIDPS using a European database. The primary endpoints were conversion rate and severe complications. Secondary endpoints

were duration of operation, overall complications, grade B/C postoperative pancreatic fistula (POPF), reoperations, duration of hospital stay, readmissions, and in-hospital mortality.

A subgroup analysis was undertaken for patients with pancreatic ductal adenocarcinoma (PDAC) to assess validated oncological quality indicators, including resection margins and number of lymph nodes harvested. Further benchmark values for core outcomes in subgroups based on centre volume (centres contributing with 100 or more, or fewer than 100 minimally invasive distal pancreatectomies), time interval (before 2016 and from 2016 onwards), and type of approach (laparoscopic or robotic) were calculated.

Variables and definitions

Preoperative variables included baseline characteristics, such as age, sex, BMI, any previous abdominal surgery, neoadjuvant treatment, dilatation of the main pancreatic duct, and ASA fitness grade¹². Several operative variables were recorded: type of approach (robotic or laparoscopic), blood transfusion, method of stump closure, multivisceral resection, vascular resection, drain positioning, and conversion.

Conversion was defined as any laparotomy for reasons other than trocar placement or specimen extraction¹³. Urgent conversion was defined as conversion for unexpected events such as bleeding. Vascular resections included resections of the portomesenteric vein, superior mesenteric vein or renal vein. Multivisceral resection was defined as distal pancreatectomy plus resection of at least one additional organ (excluding the spleen) or vascular structure because of neoplastic involvement. Postoperative complications were recorded using the Clavien–Dindo classification¹⁴; severe complications were defined as those of grade IIIa or higher. Reoperation was defined as any unscheduled surgical intervention related to pancreatic resection. The definition of POPF followed the most recent definition of the International Study Group on Pancreatic Surgery¹⁵. Complications, readmissions, and deaths were recorded during the hospital stay and up to 90 days after surgery.

Benchmark analysis

The Achievable Benchmark of Care (ABCTM; University of Alabama, Birmingham, AL, USA) method¹⁶ was used to identify the benchmarks. Briefly, this method relies on identification of the benchmark as the performance achieved by the top 10 per cent of providers adjusted for the number of patients per provider. It has already been used in different clinical, surgical, and healthcare settings^{7,17,18}.

The methodology was applied for each centre. An adjusted performance fraction (APF) was calculated by adding 1 to the number of events (numerator), and adding 2 to the number of available procedures (denominator), then dividing the first by the second of these adjusted values¹⁶. The APF was then used to sort the centres, from lowest to highest; these steps were applied for each endpoint. Using this order, the benchmark

setters were established by summing the number of procedures within the cluster for each centre, starting with the highest performer (with the lowest APF), and successively including the next highest performer, until the sum of the procedures among these highest performers comprised at least 10 per cent of the number of procedures for the cluster.

Every centre in the group whose APF was equal to or less than the APF for these highest performers was a benchmark setter for that cluster. The ABC for that group was the sum of all the adverse outcomes of the benchmark setters (numerator) divided by the sum of the number of procedures for the benchmark setters (denominator). For this purpose, centres with no complications were excluded by the benchmark assessment for those cluster analyses. The benchmark value for continuous variables (duration of operation, duration of hospital stay, number of lymph nodes harvested) was defined as the 10th percentile of the median value across centres.

Statistical analysis

The normality of data distribution was tested by means of the Kolmogorov–Smirnov test. The sample was described using median (i.q.r.) for continuous variables, and number and proportion for categorical variables. The Mann–Whitney U test was used to compare continuous skewed variables between two groups, and the Kruskal–Wallis test for comparison among three or more groups; Fisher’s exact test was used to assess the association between two categorical variables. Patients were divided into two groups depending on the BMI value (less than 30 kg/m², and 30 kg/m² or more), ASA grade (II or less, and more than II), and age (65 years or less, and over 65 years) for analysis as categorical variables. To investigate potential risk factors associated with the primary endpoints, both univariable and multivariable binary logistic regression analyses were performed for baseline characteristics of the cohort, selected on the basis of clinical knowledge. Subanalyses were subsequently undertaken for these risk factors to create new risk-adjusted benchmarks.

All statistical tests were two-tailed and $P < 0.050$ indicated statistical significance. Statistical analysis was carried out using IBM SPSS® for Windows® version 26.0 (IBM, Armonk, NY, USA) and Microsoft® Excel (Microsoft, Redmond, WA, USA).

Results

Some 1819 patients who underwent MIDPS from 31 E-MIPS centres were selected. Of these, 224 patients had been scheduled for spleen-preserving distal pancreatectomy and were thus excluded. Finally, 1595 patients were included and further considered for analysis. [Figure S1](#) shows the number of patients provided by each centre.

The study population included 667 men (41.8 per cent) and 928 women (58.2 per cent), with a median BMI of 24.8 (i.q.r. 21.8–28.4) kg/m² and a median age of 63 (51–72) years. A total of 402 patients (25.1 per cent) had an ASA grade of more than II, and 612 (31.2 per cent) had previously undergone abdominal surgery. At pathological assessment, 834 patients (52.3 per cent) had malignant lesions, of which 463 were PDACs. Overall, 53 patients with PDAC (11.5 per cent) had received neoadjuvant chemotherapy. A laparoscopic and robotic approach was used in 1306 (81.9 per cent) and 289 (18.1 per cent) patients respectively. [Table S1](#) reports clinicopathological characteristics of the entire cohort and divided by surgical approach.

Benchmark values

The overall conversion rate was 13.7 per cent (218 patients); conversion occurred in 15.1 per cent of patients after laparoscopic MIDPS and 7.3 per cent after robotic MIDPS ($P < 0.001$). Emergency conversion was required in 78 patients (5.0 per cent). The most frequent reasons for conversion were bleeding (56 patients, 25.7 per cent) and difficult dissection (49 patients, 22.5 per cent).

Overall, 897 patients (56.2 per cent) had a postoperative complication. Severe complications occurred in 276 patients (17.3 per cent). Reoperation was performed in 94 patients (5.9 per cent) and POPF was reported in 377 (23.6 per cent). The median duration of hospital stay was 8 (i.q.r. 6–11) days and 201 patients (12.6 per cent) were readmitted. Overall, 15 patients (1.0 per cent) died within 90 days of surgery or during the hospital stay.

Postoperative outcomes and benchmark assessment

[Table 1](#) shows benchmark values and percentile ranks of outcomes for MIDPS. The ABC and median values among centres were 160 and 232.5 min respectively for duration of operation, 2.5 and 12.3 per cent for conversion rate, 30.4 and 58.0 per cent for overall complications, 8.4 and 17.4 per cent for severe complications, 8.3 and 21.9 per cent for POPF, 1.8 and 5.4 per cent for reoperations, 5 and 8 days for duration of hospital stay, 4.1 and 13.0 per cent for readmissions, and 0 and 0 per cent for 90-day mortality.

In the subanalysis for PDAC, the ABC and median values were 93.9 and 66.7 per cent respectively for R0 resections, and 24 and 15 for number of lymph nodes harvested.

Benchmark subanalysis by centre volume, time interval, and type of approach are reported in [Table S2](#).

Table 1 Benchmark values and percentile ranks in minimally invasive distal pancreatectomy with splenectomy

	Range	75th percentile	50th percentile	25th percentile	Benchmark
Duration of operation (min)	132.5–361.5	275	232.5	194.5	160
Conversions (%)	0–54.5	19.2	12.3	6.5	2.5
Intraoperative blood transfusion (%)	0–10.8	6.6	2.6	0.0	0.5
Overall complications (%)	25.6–100	69.1	58.0	46.5	30.4
Severe complications (%)	4.4–54.7	25.8	17.4	13.3	8.4
POPF (%)	6.3–47.4	30.5	21.9	13.9	8.3
Reoperations (%)	0–20.0	8.7	5.4	4.1	1.8
Duration of hospital stay (days)	5–13	10	8	7	5
Readmissions (%)	0–40	17.3	13.0	7.7	4.1
90-day mortality (%)	0–17.6	2.3	0	0	0

POPF, postoperative pancreatic fistula.

Table 2 Univariable and multivariable logistic regression analyses of risk factors for conversion

	Univariable analysis		Multivariable analysis	
	OR	P	OR	P
Male sex	1.45 (1.09, 1.93)	0.010	1.48 (1.11, 1.97)	0.007
ASA grade > II	1.33 (0.96, 1.82)	0.083	1.10 (0.80, 1.51)	0.575
BMI >30 kg/m ²	2.05 (1.46, 2.87)	<0.001	2.42 (1.75, 3.35)	<0.001
Age > 65 years	1.05 (0.79, 1.40)	0.737		
Previous abdominal surgery (yes)	1.07 (0.80, 1.44)	0.645		
Neoadjuvant therapy (yes)	1.78 (0.92, 3.44)	0.084	1.81 (0.87, 3.77)	0.115
MPD diameter >3 mm	1.30 (0.95, 1.80)	0.103		
Approach (laparoscopic)	2.26 (1.42, 3.75)	<0.001	2.24 (1.51, 3.77)	<0.001
Multivisceral resection (yes)	2.41 (1.57, 3.70)	<0.001	3.04 (1.92, 4.79)	<0.001
Vascular resection (yes)	4.01 (1.64, 9.79)	0.001	8.42 (3.27, 21.67)	<0.001
Malignant disease (yes)	1.34 (1.00, 1.80)	0.048	1.00 (0.75, 1.34)	0.989
PDAC (yes)	1.19 (0.88, 1.62)	0.265		

Values in parentheses are 95 per cent confidence intervals. MPD, main pancreatic duct; PDAC, pancreatic ductal adenocarcinoma.

Table 3 Univariable and multivariable logistic regression analyses of risk factors for severe complications

	Univariable analysis		Multivariable analysis	
	OR	P	OR	P
Male sex	1.34 (1.03, 1.74)	0.027	1.28 (0.95, 1.71)	0.100
ASA grade > II	1.56 (1.17, 2.08)	0.002	1.60 (1.18, 2.19)	0.003
BMI > 30 kg/m ²	1.15 (0.83, 1.61)	0.401		
Age > 65 years	1.00 (0.77, 1.30)	0.999		
Previous abdominal surgery (yes)	1.05 (0.78, 1.37)	0.749		
Neoadjuvant therapy (yes)	1.03 (0.49, 2.13)	0.948		
MPD diameter >3 mm	1.27 (0.94, 1.71)	0.122		
Approach (robotic)	1.71 (1.26, 2.33)	<0.001	1.87 (1.34, 2.60)	<0.001
Intraoperative blood transfusion (yes)	1.86 (1.06, 3.25)	0.029	1.36 (0.73, 2.55)	0.337
Stump closure with stapler (yes)	0.82 (0.59, 1.15)	0.386		
Stump oversewn (yes)	0.98 (0.66, 1.44)	0.905		
Multivisceral resection (yes)	1.87 (1.23, 2.84)	0.003	1.88 (1.16, 3.04)	0.010
Vascular resections (yes)	1.51 (0.55, 4.15)	0.425		
Drain (yes)	0.53 (0.16, 1.70)	0.275		
Conversion (yes)	1.33 (0.94, 1.90)	0.111		
Emergency conversion (yes)	0.90 (0.48, 1.69)	0.747		
Malignant (yes)	1.02 (0.79, 1.33)	0.863		
PDAC (yes)	1.07 (0.80, 1.42)	0.654		

Values in parentheses are 95 per cent confidence intervals. MPD, main pancreatic duct; PDAC, pancreatic ductal adenocarcinoma.

Table 4 Risk-adjusted benchmarks and percentile ranks for risk groups associated with conversion and severe complications

	Rate (%)				
	Range	75th percentile	50th percentile	25th percentile	Benchmark
Conversions					
Male sex	2.7–57.1	12.2	19.8	25	2.8
BMI > 30 kg/m ²	0–50.0	10.0	25.0	36.7	7.5
Multivisceral resection	0–100	8.1	33.3	50.0	6.3
Laparoscopy	0–66.7	7.1	12.9	23.1	2.9
Severe complications					
ASA grade > II	6.25–75	16.4	25.0	33.3	9.8
Multivisceral resections	11.1–100	21.4	40.0	60.0	13.3
Robotic resections	8–54.8	17.1	25.0	33.3	11.3

Univariable and multivariable analysis of conversion and severe morbidity

Univariable analysis showed that the conversion rate was associated with male sex, BMI over 30 kg/m², laparoscopic approach, multivisceral resections, vascular resections, and malignant disease (Table 2). In multivariable analysis, five risk factors were independently associated with an increased risk of conversion (Table 2): male sex (OR 1.481, 95 per cent c.i. 1.113 to

1.969), BMI above 30 kg/m² (OR 2.422, 1.752 to 3.349), laparoscopic approach (OR 2.244, 1.507 to 3.343), multivisceral resection (OR 3.035, 1.923 to 4.790), and vascular resection (OR 8.416, 3.267 to 21.672).

Male sex, ASA grade above II, robotic approach, intraoperative blood transfusion, and multivisceral resection were associated with a higher risk of severe morbidity in univariable analysis (Table 3). In multivariable analysis, only ASA grade over II (OR 1.604, 1.175 to 2.190), robotic approach (OR 1.867, 1.342 to 2.599),

and multivisceral resection (OR 1.879, 1.163 to 3.036) were independently associated with severe complications.

Risk-adjusted benchmark analysis

ABCs for conversion were calculated in the following clusters: male sex, BMI exceeding 30 kg/m², multivisceral resection, and laparoscopy. Benchmarks for conversion in patients undergoing vascular resections were not determined because of the small sample size. The ABCs and median values for conversion rate were 2.8 and 19.8 per cent respectively for men, 7.5 and 25.0 per cent when BMI was above 30 kg/m², 6.3 and 33.3 per cent for procedures with associated multivisceral resection, and 2.9 and 12.7 per cent for laparoscopy.

ABCs for severe morbidity were calculated in the following clusters: ASA grade over II, multivisceral resection, and robotic resection. The ABCs and median values for severe morbidity were 9.8 and 25.0 per cent respectively for patients with an ASA grade of II, 13.3 and 40 per cent for procedures with associated multivisceral resection, and 11.3 and 25.0 per cent for robotic resections.

Benchmark values and percentile ranks for conversion and severe morbidity after risk adjustment are reported in [Table 4](#).

Discussion

This multicentre study investigating benchmark values for MIDPS reported the best achievable surgical outcomes, which included a conversion rate of 2.5 per cent and a severe complication rate of 8.4 per cent. The findings also suggested ABC values of 160 min for operating time, 8.3 per cent for POPF, 1.8 per cent for reoperation, and 0 per cent for mortality.

The recent evidence-based Miami guidelines¹⁹ recommend minimally invasive distal pancreatectomy over the open approach, because of better short-term postoperative outcomes for both the laparoscopic and robotic approaches. Although the superiority of the minimally invasive approach was clear^{20,21}, the intraoperative and postoperative outcomes varied widely on the basis of several variables, such as centre volume, indication for surgery, and patient and tumour characteristics^{22–24}. In two recent RCTs^{22,23}, the median duration of operation ranged from 120 to 217 min, and the rate of severe complications, POPF, and readmission ranged from 13.7 to 25, 31 to 39, and 4 to 15 per cent respectively. Consistent with these data in the present study, the median operating time was 232 min, and median rates of severe complications, POPF, and readmission were 17.4, 21.9, and 13.0 per cent respectively. In contrast, previous studies^{22,23}, both prospective randomized and retrospective, reported a postoperative mortality rate of 0 per cent; similarly, in the present analysis, the ABC value for 90-day postoperative mortality was 0 per cent. However, this variability in postoperative outcomes well reflected the clinical outcomes of a large population of patients undergoing minimally invasive distal pancreatectomy, but did not allow definition of the best standard of care.

Benchmarking is a well established tool for setting standards of excellence. Owing to its complexity, leading to a high postoperative complication rate, prolonged hospital stay, and relevant costs²⁵, pancreatic surgery represents an ideal application for benchmarking. In this field, reference values have been set for pancreatoduodenectomy with and without portomesenteric venous resection^{3,4}; to date, no benchmarks have been defined for distal pancreatectomy.

Different methods have been described for determining benchmarks in healthcare, mainly depending on the cohort on which they were calculated. Benchmarks for

pancreatoduodenectomy^{3,4} were based on the postoperative outcomes of the 'best patients', a well selected population of low-risk patients in terms of surgical and clinical characteristics (38 per cent of the entire cohort of patients undergoing pancreatoduodenectomy³), treated in the 'best centres', a limited number of high-volume units performing more than 50 pancreatic resections per year. The authors defined the benchmark value for each outcome as the 75th percentile of the median value across centres. On the contrary, the present analysis was based on the ABC methodology, which defined the benchmark as the result achieved by the best 10 per cent of providers adjusted for the number of patients per centre. It was carried out on the entire unselected population of patients undergoing MIDPS included in the European E-MIPS database, which gathered data from pancreatic units with different caseloads. The ABC method best adhered to the authors' needs, as all high-performance centres contributed to the benchmark setting, but the impact of those contributing a small number of procedures was limited, thus reducing their potential for a disproportionate impact on the values obtained. The ABC method could be suggested to better reflect real-world clinical practice in comparison to the other method reported, as it may be misleading to compare the benchmark derived from low-risk patients operated only in high-volume referral centres with real-life surgical patients²⁶.

Because of the great variability in terms of surgical and patient characteristics that can potentially affect postoperative outcomes, a homogeneous population of patients undergoing a very specific procedure such as MIDPS was considered. In particular, it was decided to exclude both patients undergoing spleen-preserving distal pancreatectomy and those with intended spleen preservation from this analysis, because spleen preservation has been described as a protective factor for the occurrence of postoperative complications, especially POPF^{24,27}. Moreover, the intraoperative decision to perform splenectomy in a patient in whom preservation of the spleen was intended can be based on an unexpected complication, such as bleeding, or made for oncological reasons; in both scenarios, several further variables would be introduced into the analysis with an augmented risk of bias.

In addition, among the cohort of patients undergoing MIDPS, many factors could influence the achievable outcomes, so a risk-adjusted evaluation was applied for the primary endpoints. Consistent with previous literature²⁸, male sex, BMI over 30 kg/m², laparoscopic approach, multivisceral resection, and vascular resection were independently associated with an increased risk of conversion, whereas ASA grade over II, robotic approach, and multivisceral resection were independently associated with severe complications. Rather than excluding these high-risk patients from the analysis, stratified benchmark values were specifically calculated on these subgroups, consequently with worse results in comparison with those for the entire cohort. This suggested a potential dynamic application of benchmarking, rather than a rigid cut-off not to be exceeded; it could help to define groups of patients in whom less outstanding outcomes could be achieved, stimulating the surgeon to improve patients selection and perioperative management, or to provide more accurate counselling. Moreover, it could be useful in comparison of benchmark results between centres, in order to stratify specific high-risk patients into separate categories. A further subanalysis was run in the cohort of patients with PDAC to assess specific benchmarks for R1 rate and number of lymph nodes harvested, as these are critical outcomes for oncological adequacy. However, margin status is strongly affected by the pathological evaluation, and thus potentially biased by the protocols adopted and the accuracy of pathology among different

centres as well as the time span of the study²⁹. Further prospective studies, based on strict and homogeneous pathological protocols, may address the issue of oncological adequacy and hopefully guarantee more consistent results.

This study has some limitations. First, it carries the inherent bias of a multicentre retrospective study. The wide enrolment period may have introduced some bias: the different centres may have started to perform minimally invasive pancreatic surgery in different periods, and some may have participated in the E-MIPS database only in recent years, potentially including only a proportion of the patients who actually underwent surgery during the study interval. In addition, the more recent introduction of the robotic compared with the laparoscopic approach could have led to a potential learning curve effect, accounting for the greater complication rate after robotic MIDPS. Although the study focused on a selected group of patients undergoing a specific intervention, some unknown confounders may have affected the outcomes and risk adjustment evaluation. From this perspective, in the absence of an *a priori* definition of discharge criteria, duration of hospital stay may have been affected by social, logistical, and cultural factors that may differ substantially between departments and countries. In the future, this benchmark could be evaluated by considering the time to functional recovery rather than the effective discharge date. Considering this heterogeneity, the short duration of stay should be considered in the light of related outcomes, such as readmission. Similarly, the high rate of planned MIDPS in patients without malignancies deserves further investigation, with the aim of understanding whether potential associated conditions leading to splenectomy, such as symptoms, were present or whether the indication was wrong, offering a hint for another crucial benchmark, such as 'surgical overtreatment' or 'inadequate indication for surgery'. The future strategy for defining benchmarks depends on international registries, in order to guarantee up-to-date, objective, uniform, and complete data collection². Second, because of its novelty, consensus regarding the methodology used for benchmarking of surgical procedures is lacking, and the present results may not be comparable to those of other similar studies. Finally, the results reflect the best outcomes that can be achieved in certain time interval; they must be revised periodically in relation to future advances.

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Supplementary material

Supplementary material is available at *BJS* online.

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