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ORIGINAL ARTICLE

Application of minimally invasive pancreatic surgery: an Italian survey

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Abstract

The value of minimally invasive pancreatic surgery (MIPS) is still debated. To assess the diffusion of MIPS in Italy and identify the barriers preventing wider implementation, a questionnaire was developed under the auspices of three Scientific Societies (AISP, It-IHPBA, SICE) and was sent to the largest possible number of Italian surgeons also using the mailing list of the two main Italian Surgical Societies (SIC and ACOI). The questionnaire consisted of 25 questions assessing: centre characteristics, facilities and technologies, type of MIPS performed, surgical techniques employed and opinions on the present and future value of MIPS. Only one reply per unit was considered. Fifty-five units answered the questionnaire. While 54 units (98.2%) declared to perform MIPS, the majority of responders were not dedicated to pancreatic surgery. Twenty-five units (45.5%) performed < 20 pancreatic resections/year and 39 (70.9%) < 10 MIPS per year. Forty-nine units (89.1%) performed at least one minimally invasive (MI) distal pancreatectomy (DP), and 10 (18.2%) at least one MI pancreatoduodenectomy (PD). Robotic assistance was used in 18 units (31.7%) (14 DP, 7 PD). The major constraints limiting the diffusion of MIPS were the intrinsic difficulty of the technique and the lack of specific training. The overall value of MIPS was highly rated. Our survey illustrates the current diffusion of MIPS in Italy and underlines the great interest for this approach. Further diffusion of MIPS requires the implementation of standardized protocols of training. Creation of a prospective National Registry should also be considered.

Keywords Minimally invasive surgery · Laparoscopy · Robotic surgery · Pancreatic surgery · Survey · Italy

Introduction

Laparoscopic pancreatoduodenectomy (PD) [1] and laparoscopic distal pancreatectomy (DP) [2] were both first reported in 1994. After a quite long period of gestation, minimally invasive pancreatic surgery (MIPS) is eventually gaining momentum as it is performed at a growing number of institutions worldwide [3]. As for most new procedures, the early diffusion of MIPS had to go through to the S-shaped curve associated with the adoption of innovation [4]. What was somewhat new and quite specific to MIPS was that the early development of these procedures did not involve dedicated pancreatic surgeons and was instead mostly left to general surgeons with laparoscopic and/or robotic skills, who were neither practicing pancreatic surgery truly at high volumes nor being fully dedicated to pancreatic diseases. So, while pancreatic surgery was quickly developing into a sub-specialization of hepato-pancreato-biliary surgery [5, 6], the development of MIPS was left to surgeons typically able to master minimally invasive techniques, but not necessarily competent and proficient in pancreatic surgery. The quite unregulated adoption of MIPS sometimes led to unsatisfactory results [7], further slowing the systematic adoption of these procedures at high-volume institutions. The rise of a new generation of pancreatic surgeons with laparoscopic [8,

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9] and/or robotic skills [10, 11] started the new, and current era of MIPS. The ensuing enthusiasm on MIPS was such that on April 20th, 2016 the IHPBA (International Hepato-Pancreato-Biliary Association) organized the first international state-of-the-art conference on minimally invasive pancreatic resection in São Paulo, Brazil [12]. Although this conference was initially conceived as a "consensus conference", and subsequently converted into a "state-of-the-art conference" because of lack of compelling evidence to allow for a benefit-risk assessment of MIPS [13], the commitment of IHPBA to scrutinize and regulate this area is perhaps the best evidence that MIPS has reached the stage of development when abortion is no longer possible.

Materials and methods

A specific questionnaire was developed by three national societies involved in minimally invasive and pancreatic surgery: "Associazione Italiana Studio Pancreas" (AISP), "Italy National Chapter of International Hepato-Pancreato-Biliary Association" (It-IHPBA), and "Societa' Italiana di Chirurgia Endoscopica" (SICE). In July 2016, the questionnaire was sent to the members of each of these societies and to the members of the two major Italian surgical societies: "Societa' Italiana di Chirurgia" (SIC) and "Associazione Chirurghi Ospedalieri Italiani" (ACOI). It was specified that only one questionnaire had to be compiled for each surgical unit, and submitted to a specific e-mail account (igomips@gmail.com) with the agreement of all the members of the surgical team.

The questionnaire consisted of 25 questions investigating: general characteristics of each hospital, pattern of surgical activity carried out at each unit, annual volume of pancreatic resections, proportion of pancreatic resections with respect to the overall volume of activity, available facilities and technologies, and type of MIPS performed; opinions regarding the present and future value of MIPS. A complete copy of the questionnaire in the original language is presented in the supplementary material (doc. 1). Subjective assessment of the value of the minimally invasive (MI) technique in various fields was performed using a visual analogue scale from 0 to 10 [14]. We received 56 answers but in one case the questionnaire was empty; the author specified that due to the centralization strategy adopted in his region, his unit was not allowed to perform pancreatic surgery. We excluded that case from further analysis. All the data were centrally collected in May 2017 and imported into a specific electronic database. A second check was made to rule out imputation error and multiple reporting by a second author. Data were analyzed in a descriptive way, utilizing the statistical software SPSS™ (IBM). Categorical data are reported as number with percentage. Normally distributed continuous data are reported as mean ± standard deviation (SD).

Results

Participants

Fifty-five surgical units located in 14 different regions answered the questionnaire. Their main characteristics are displayed in Table 1. Unfortunately because many surgeons

Table 1 Characteristics of the 55 participating surgical units

Characteristic	No. (%)
Public hospital	43 (78.2)
Private hospital	12 (21.8)
University centre	10 (18.2)
Hospital size (bed capacity)	
≤ 300	5 (9.1)
300–500	17 (30.9)
501–1000	19 (34.5)
> 1000	14 (25.5)
Availability of a minimally invasive training facility/simulation centre	25 (45.5)
Availability of a robotic system	29 (52.7)
Performing minimally invasive surgery for other complex procedures	52 (94.5)
Percentage of pancreatic surgery on the overall volume of the unit	
< 5%	20 (36.4)
5–10%	17 (30.9)
11–20%	9 (16.4)
21–75%	4 (7.2)
> 75%	5 (9.1)

are members of more than one society and because the number of surgical units that received the questionnaire is not calculable, it was not possible to estimate an answer rate. However, we know from published data of the Ministry of Health [15] that, in 2015, 88 hospitals in Italy had a bed capacity for acute illness higher than 500. In our cohort, 23 units belonged to this group of hospitals, and this denotes a discrete adherence to the survey, at least by major hospitals.

The majority of the units that answered the survey were not dedicated to pancreatic surgery. This type of surgery accounts for less than the 10% of the total activity in 37 (67.3%) of hospitals. On the other hand, nearly all responders declared to have sound experience in advanced minimally invasive procedures that were performed at 52 units (94.5%). Twenty-five (45.5%) of the responders declared also to have access to a simulation centre for formation/training on MI surgery.

Surgical volume

The annual volume of pancreatic resections, overall and minimally invasive, declared by each unit is shown in Fig. 1. Nearly half of the units (25: 45.5%) performed < 20 pancreatic resections per year. Thirty-nine (70.9%) performed < 10 MIPS per year.

MIPS

MIPS was performed in 54 out of 55 responding units (98.1%). Laparoscopy was used in 52 (96.2%) units and robotic assistance in 18 units (33.3%). Thirty-six units used only laparoscopy (66.6%), 16 both laparoscopy and robotic assistance (29.6%), and 2 only robotic assistance (3.7%). When these data were confronted with declared availability of a robotic system (29/54; 53.7%), it appeared that robotic assistance was not used in 11 units embedded in hospitals owing this type of technology (37.9%). On the other hand, robotic assistance was used in seven out of ten units performing also PDs (70.0%).

Two units reported to have used hand-assistance during laparoscopic procedures and four units the adoption of a hybrid technique with open reconstruction through a small incision after either laparoscopic ($n = 3$) or robotic ($n = 1$) dissection.

Forty-nine units (89.1%) declared to have performed at least one minimally invasive DP, and ten units (18.2%) at least one minimally PD. Of the 49 units that performed at least a DP, 19 did not perform any other major pancreatic resections or visceral anastomosis MI. The complete list of minimally invasive procedures performed to address a pancreatic disease is provided in Table 2.

Robotic surgery

A robotic system was available in 29 hospitals hosting responding units. Eighteen units (62.0%) were using the robot for minimally invasive pancreatic procedures, nine (31.0%) were willing to implement robotic assistance, and two (6.8%) were not interested in exploring the potential of this technology.

Fourteen units had used the robotic system to perform at least one DP, and seven to perform at least one PD. The complete list of pancreatic procedures carried out using robotic assistance is provided in Table 3.

The survey included a specific question inquiring whether or not robotic assistance was believed to provide advantages when compared to laparoscopy. Robotic assistance was deemed advantageous by 25 units for DP (45.5%), by 35

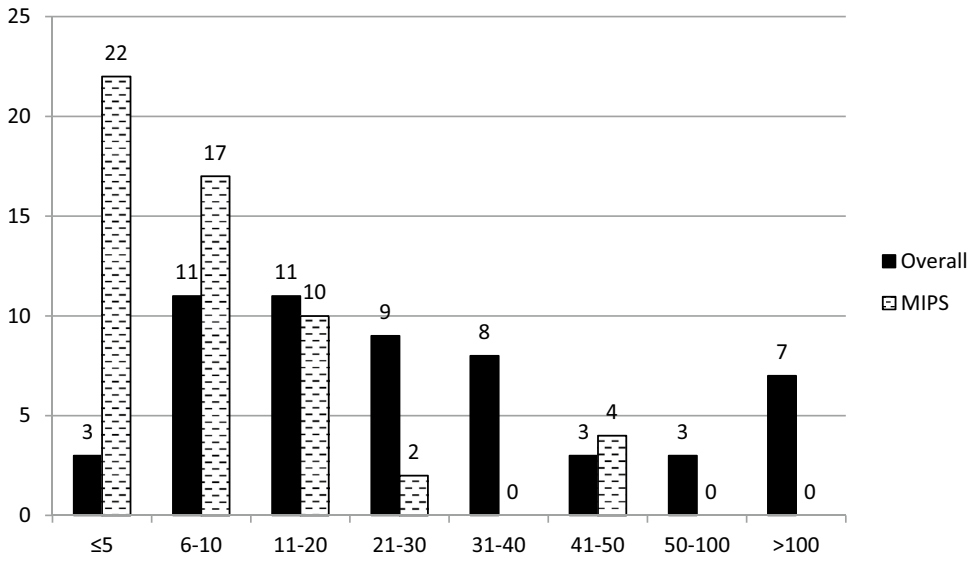

Fig. 1 Categorization of responding units based on number of pancreatic resections performed per year, either overall (black bars) or MIPS (dotted bars)

Table 2 Type of minimally invasive pancreatic procedures performed

Procedure	No. (%)
Distal pancreatectomy	49 (89.1)
Exploratory/diagnostic laparoscopy	48 (87.3)
Spleen preserving distal pancreatectomy without vessels sacrifice	41 (74.5)
Enucleation	40 (72.7)
Digestive bypass	23 (41.8)
Enteric drainage of pancreatic pseudocysts	12 (21.8)
Biliary bypass	11 (20.0)
Pancreaticoduodenectomy	10 (18.2)
Spleen preserving distal pancreatectomy with vessels sacrifice (Warshaw)	10 (18.2)
Necrosectomy	10 (18.2)
Ampullectomy	5 (9.1)
Termoablation	5 (9.1)
Total pancreatectomy	5 (9.1)
Central pancreatectomy	4 (7.3)
Total pancreatectomy with vascular reconstruction	3 (5.5)
Pancreaticoduodenectomy with vascular reconstruction	2 (3.6)
Distal pancreatectomy with the resection of the celiac trunk (Appleby)	1 (1.8)

Table 3 Use of robotic assistance in minimally invasive pancreatic procedures

Procedure	No. (%)
Distal pancreatectomy	14 (25.5)
Spleen preserving distal pancreatectomy without vessels sacrifice	14 (25.5)
Enucleation	12 (21.8)
Pancreaticoduodenectomy	7 (12.7)
Bypass/pseudocyst drainage	3 (5.5)
Central pancreatectomy	3 (5.5)
Total pancreatectomy	3 (5.5)
Spleen preserving distal pancreatectomy with vessels sacrifice (Warshaw)	1 (1.8)

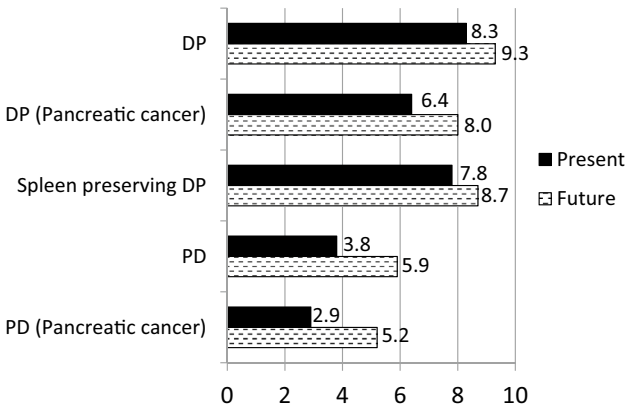

Fig. 2 Present (black bars) and future (dotted bars) perceived value of selected minimally pancreatic procedures

units (63.6%) for DP with preservation of the spleen and the splenic vessels, and by 41 units for PD (74.5%).

Perceived value of MIPS and obstacles to further implementation

Several questions were given to assess current and future value of MIPS. Opinions were provided using a visual scale from 0 to 10, where 0 corresponded to no value and 10 to the greatest possible value.

As shown in Fig. 2, both present and future value of MIPS for DP was rated highly. The current value of PD was instead quite low, with some improvement in future perspectives. When opinions on the value of PD were limited to units already performing this procedure, the present mean value increased from 3.8 to 5.5, while the future mean value increased from 5.5 to 7.2. The same figures in the setting of pancreatic cancer were: present value from 2.9 to 4.2; future value from 5.5 to 6.5.

The most frequently reported barriers to the diffusion of MIPS were the intrinsic difficulty of the technique and the lack of specific training. The complete list of the reported barriers is shown in Table 4 (multiple choices were possible). The survey included also the option to select a field named "other reasons" for items not specified in the questionnaire. In this field, three units reported that low volume was an issue, because of the steep learning curve associated with the implementation of MIPS. Two units also reported discordant opinions among the members of the same team as a barrier to MIPS.

Table 4 Perceived barriers to the diffusion of MIPS (multiple choices were possible)

Barrier	No. (%)
Complexity of the technique	35 (63.6)
Lack of specific training	31 (56.4)
Costs	25 (45.5)
Lack of support from the management	22 (40.0)
Lack of operative-room time	20 (36.4)
Lack of evidence of oncologic efficacy	17 (30.9)
Lack of evidence of safety	14 (25.5)
Lack of interest	10 (18.2)
Other	5 (9.1)

Discussion

Our survey shows the current diffusion of MIPS in Italy. The global picture demonstrates that many centers already have an experience with MIPS and that some institutions also include very complex procedures, such as PD. On the whole, there is a good level of interest in MIPS and already a quite diffused use of these techniques in the country.

In Italy, MIPS is currently performed both in general surgery units, with experience in advanced minimally invasive procedures, and in referral centers for pancreatic diseases. As expected, general surgery units are prevalent over dedicated institutions, with respect to number of involved centers. However, these general surgery units are often based at hospitals where pancreatic procedures are not performed at high volumes. In the worldwide survey on MIPS [3], the average hospital volume for pancreatic resections was 50 for the institutions involved also in MIPS. In our survey, only ten units performed > 50 pancreatic resections per year. The limited annual volume of pancreatic procedures carries several concerns, the most relevant being safety. Indeed, two studies from the US identified the hospital volume threshold for minimally invasive PD in 10 and 22 procedures per year, respectively [16, 17]. Considering the higher cut-off value of 22 procedures, currently in Italy, there would be only one unit entitled to perform minimally invasive PD. These data are also quite in keeping with number of procedures required to overcome the learning curve for minimally invasive PD, as approximately 50 procedures are required for laparoscopic PD [18] and around 40 for robotic PD [19, 20]. These figures clearly suggest the need for centralization of minimally invasive PD as well as for the implementation of a program of systematic training according to the principles set by the IHPBA state-of-the-art conference [21] and following the example provided by Dutch surgeons [22].

As the learning curve for MI DP requires between 10 and 15 cases [23, 24] and the overall safety profile of DP is superior when compared to that of PD, fewer concerns should surround MI DP on the side of safety. Despite this, 39 out 54 units reported < 10 MIPS per year rising volume-related concerns on completion of individual and institutional learning curve. Additionally, DP includes a quite diverse spectrum of procedures ranging from straightforward operations in "easy to operate" patients to overwhelming difficult surgeries in "surgically hostile" patients [25] making a good margin of safety anyway mandatory. Considerations on patients safety, although key, do not consider all the other relevant outcome metrics in DP such as appropriateness of surgical indication, rate of exploratory/palliative surgery, incidence and severity of all post-operative complications and in particular post-operative pancreatic fistula, rate of spleen preservation in suitable patients, rate of margin negative resection and number of examined lymph nodes in patients with malignant tumors, and so forth. Some of the shortcomings associated with low volume can be surpassed by cooperation among centers, as shown in several examples provided also by our country. In one paradigm, the skills of a team with good experience in laparoscopy are brought in the context of a high-volume, traditional, center for pancreatic surgery to facilitate and speed up the implementation of MIPS [26]. The somewhat opposite approach is proctoring of a low volume center by a high-volume center for pancreatic surgery, having also sound skills in MIPS [27]. Both these strategies were shown to work efficiently. Our results support the value of this virtuous type of cooperation. The fact that almost all the participating units, that are not dedicated centers, performed at least one MI DP and half of them did not perform any other major pancreatic procedure MI suggest that MI DP is considered by Italian surgeons a procedure that does not require referral centers or specific training. Nevertheless, DP is a challenging procedure with a risk of over-indication and a high rate of post-operative morbidity. A shared knowledge, guidelines and collaboration among different centers could be the key factors to overcome the concerns this survey can rise. Our survey demonstrated that several MI procedures, other than DP or PD, are performed quite frequently in Italy. It was indeed quite unexpected that over 40% of responders declared to practice MI gastrojejunal bypass surgery, approximately 20% biliary bypass or internal drainage of pancreatic pseudocysts, and 20% necrosectomy in the setting of severe pancreatitis. Looking at these data as a whole, the global picture of MIPS in Italy is much more relevant than just a different approach to perform DP and, sometimes, PD. Although current and future opinions on the value of MIPS still show the presence of main concerns, especially for PD and in the setting on cancer, on the other hand, our data unambiguously demonstrate that MIPS in Italy is here to stay. Another important piece of information provided from this surgery regards the opinions on the value of robotic assistance. If over 60% of the units with a robot were already using robotic assistance for some of

their MIPS, approximately 30% were willing to implement the use of the robot, while just < 10% were not interested in this technology. The advantage of robotic assistance was scored higher for procedures including complex dissections and multiple intracorporeal sutures, such as for DP with preservation of the spleen and the splenic vessels (63.6%) and for PD (74.5%). These opinions cannot reply to the very complex question on cost-effectiveness of robotic assistance in MIPS, but show that robotic surgery is expected to play a role in the future on MIPS.

The results of our survey should be interpreted also in the light of some weakness of our study. By definition, the units that decided to participate are a selected population, as they represent the centres more interested in the topic and probably more familiar with it. Despite having used the most reliable and universal database for surgical institutions available in Italy, we cannot be completely sure to have reached all centers, so that we cannot provide a fully reliable answering rate.

In conclusion, our survey underscores both the great interest for MIPS in Italy and the presence of problems related to the training and the diffusion of this approach. Our findings support the need for the creation of a prospective national registry for MIPS. As already shown for the liver, the implementation of a national registry is expected to result in the creation of a solid infrastructure for collaborative research and education [28].

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Research involving human participants and/or animals This article does not contain any studies with human participants or animals performed by any of the authors.

Informed consent For this type of study formal consent is not required.

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