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Complications after duodenopancreatectomy within eras protocols in a developing country

Abstract

Background: Recent studies have suggested that intraoperative fluid overload is associated with the presence of postoperative pancreatic fistula after duodenopancreatectomy. Finding the ideal balance between hypoperfusion and tissue edema with fluids administration during major gastrointestinal surgery is challenging. The aim of this study was to evaluate whether intraoperative fluid management along with enhanced recovery protocols could affect the outcome after a major pancreatic resection.

Methods: Data from 67 consecutive patients who underwent duodenopancreatectomy from January 2012 to January 2017 were analyzed.

Patients were divided into two groups according to the use of enhanced recovery after surgery protocols. Patients in ERAS protocols had a fluid therapy algorithm which consists: Systolic Volume Variation (SVV) less than 13%, Cardiac Index (CI) higher than 2.5 L/Min/M2 and Delta CO2 less than 6 mmHg.

Results: A total of 67 patients were analyzed from July 2012 to January 2017, of these 49.3 % correspond to the female gender. The most frequent diagnosis was Pancreatic Cancer n:48 (71.6%), followed by Intraductal Papillary Mucinous Neoplasm (IPMN) n:6 (9%). The majority of patients were in the ERAS Group with a total of 46 patients (68.7%). In the ERAS group, 80.4% and 95.7% did not develop POPF and Delayed Gastric Emptying (DGE) respectively. The incidence of POFP in all the patients was 11.94% (Grade A are considered biochemical leak and NOT a proper fistula). The incidence of DGE was 11.94%. The probability of intraoperative blood loss less than 300ml was higher in the ERAS group; however, the probability to need a transfusion was lower in the ERAS Group. The probability to use less than 5000ml of fluid therapy was higher in the ERAS group. The total length of stay was statistically significant shorter in the ERAS group. No differences in 30-days mortality were found.

Conclusion: The implementation of ERAS protocols in PD did show a decrease in intraoperative blood loss, intravenous fluids therapy, need for transfusion, DGE, and total hospital stay; however, intraoperative fluid restriction in PD did not show to significantly affect POPF.

Keywords: pancreaticoduodenectomy, therapy, fistula, enhanced recovery after surgery

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Introduction

Enhanced recovery after surgery (ERAS) protocols intention is to optimize the recovery of patients with less morbidity and mortality. Recent studies have suggested that intraoperative fluid overload could be associated with the development of pancreatic fistula (POPF) after duodenopancreatectomy (DP).[1] Delayed gastric emptying (DGE) despite its causes are not completely clear and not being an imminent life threatening complication after DP, its reported incidence ranges from 3.2% to 59% accordingly to the definition used.[2] In recent years the trends in fluid therapy in the operating room in complex patients has been a focal point, but we think perioperative fluids it is only one of the multiple variables in the presentation of a POPF. Given this, we consider comparing two types of management in patients undergoing DP, one with standard protocol and another group with ERAS protocols. The importance of this study is to present our Latin American data considering that is not evidence in our continent about this topic.[1–3] The purpose of this study is to find how to mitigate this type of complications. Therefore, we hypothesized that implementation of ERAS strategies along with intraoperative fluid management could decrease the development POPF.

Methods

Patient's selection

Data from 67 consecutive patients who underwent DP from January 2012 to January 2017 from the Department of HPB surgery at Clinic CES in Medellin, Colombia, were analyzed. Patients scheduled for DP in whom total pancreatectomy was performed instead were excluded from this analysis. Patients in whom DP were performed by general surgeons were also excluded. All the operations analyzed were performed by the same surgical team composed by two HPB surgeons and two HPB anesthesiologist. Patients were divided in two groups according to the utilization of ERAS protocols.

Anesthesiologist protocols

Patients in which ERAS protocols were not applied (Group No-ERAS), had an 8-hours fasting time either for liquids and solids. No carbohydrates load was administered. Basic patient education about the operation was given by surgeons and anesthesiologist. Intravenous fluids were liberally used during the operation and vasopressors were administered according to the anesthesiologist criteria. Patients in

ERAS protocols (Group ERAS) followed the recommended guidelines of the ERAS society.[4,5] A nutritional evaluation was performed at least 2 weeks before the operation. Ecoimmunonutrition, including pre-biotics and Argynine supplements, were prescribed. Patient education was provided by surgeons and anesthesiologist, in which intra and postoperative aspects were explained. Preoperative fasting time was 8 hours for solids and 2 hours for liquids. Maltodextrins load was offered 2 hours before the operation. Cardiac Output monitor was used (EV1000, Edwards Lifesciences) to guide fluid therapy according to the following algorithm: Systolic Volume Variation (SVV) less than 13% was kept as a goal, along with a Cardiac Index (CI) higher than 2.5 L/Min/H and Delta CO2 less than 6 mmHg. Intravenous fluids were given using balanced solutions (Isofundin, Braun) at a 2 ml/K/h rate. A fluid bolus of 3 ml/K was infused to reach goals if necessary. Noradrenaline was used in tritable doses in case of systolic pressure less than 90 mmHg and if intravenous fluids goals were reached. However, it was frequently stopped once the procedure was completed. Orotracheal intubation was performed in all patients with balanced anesthesia using Remifentanil with Target Control Infusion (TCI) between 3–5ng/ml and Sevoflurane to keep 0.8 MAC aspirated. Muscle relaxation was achieved with Rocuronium or Cisatracurium. Mechanical ventilation was controlled with Tidal Volume 6–8 ml/kg, respiratory rate 12–14/min and PEEP 5 mmHg to reached ETCO2 35 mmHg. All patients were monitored with central venous pressure and arterial line. Esophageal temperature, pneumatic compressive socks, and bladder catheter were used in all patients. Thoracic epidural analgesia (T7-T8), with an initial bolus of 10-15 ml of Bupivacaine, followed with an infusion of bupivacaine 0,125% between 6–8 ml/h. Intraoperative arterial blood gases, lactate, and electrolytes were measured. All patients were transferred to the intensive care unit after the operation was finished.

Surgical protocols

Access to the abdominal cavity was reached through a bilateral subcostal incision. After a full Kocher's manoeuver and artery first approach, the stomach was transected and stapled 3 cm above pylorus, D1 lymph node resection was routinely performed in all oncologic cases, followed by cholecystectomy and standard transection of bile duct and jejunum. Pancreatic transection was made with a scalpel and parenchyma hemostasis was achieved with 6/0 Prolene stitches. Pancreatic anastomosis was performed according to risk factors for postoperative pancreatic fistula (PPF)(1), Double-layer invaginated pancreaticogastrostomy (PG) was performed in high-risk pancreas and duct-to-mucosa pancreatojejunostomy (PJ) in low-risk pancreas.[6] One silastic drain was left close to the pancreatic anastomosis in patients of the ERAS group and two drains for the pancreatic and bile duct anastomosis respectively in patients from the No-ERAS group.

Pancreatic fistula definition reported by the International Study Group of Pancreatic Surgery (ISGPS) in 2016 was used for this analysis as follows: Biochemical leak (formerly known as grade A POPF) refers to an amylase in drain fluid >3 times the upper limit of institutional normal serum amylase value in a patient otherwise well without clinically relevant symptoms secondary to this leak. Grade B is a proper fistula with persistent drainage >3 weeks with clinically relevant changes in the management of POPF, requiring percutaneous or endoscopic drainage, signs of infection without organ failure. If reoperation, organ failure or death occurs grade B shifts to grade C POPF. ISGPS definition of DGE was also used in this study as follows. Grade A DGE: if nasogastric tube (NGT) is required between post operative days (POD) 4 to 7 or reinsertion was necessary after removal by POD 3 and the patient is unable to tolerate solid diet on POD 7 but resumes it before POD 14. Grade B DGE: if NGT is required between POD 8-14, and reinsertion after POD 7 or solids diet is not tolerated by POD 14 but is resumed before POD 21. Grade C: NGT cannot be removed or has to be reinserted after POD 14 or if at POD 21 complete oral intake cannot be achieved.

Statistical protocols

Demographic, clinical and intraoperative variables were retrospectively collected. Fluid therapy below 5000 ml and intraoperative bleeding above 600 ml were also recorded. Postoperative variables included hospital stay, reintervention, and 30-day mortality and were also included in a multivariate analysis. Normality distribution was evaluated with the Shapiro Wilk test. T-student, Chi2, U-mann Whitney and logistic regression test were used where applicable using SPSS® version 24 for macintosh. Alpha values below 0.05 were considered statistically significant. Protocols for this observational study were approved by the institutional ethics committee following national guidelines.[7,8]

Results

A Total of 67 patients were analyzed from July 2012 to January 2017. 49.3% were female, with a median age of 58.2 years old (SD 12.5 years). The most frequent diagnosis was Pancreatic Cancer n:48 (71.6%), followed by Intraductal Papillary Mucinous Neoplasm (IPMN) n:6 (9%). ERAS Group included 46 patients (68.7%) (Table 1). In the ERAS group 80.4% and 95.7% did not develop POPF and DGE, respectively. Seven out of 46 patients (15.2%) in the ERAS group and 1 out of 21 (4.7%) in the No ERAS group developed grade B or C POPF, respectively (p=0.41; OR 1.7, IC95% 0.32-9.0). Two patients out of 46 in ERAS group and 6 out of 21 in the No ERAS group developed DGE (p=0.009; OR 0.1, IC95% 0.02-0.62). The overall incidence of either POFP or DGE was 11.94% and 11.94%, respectively. The probability of intraoperative blood loss less than 300ml was higher in the ERAS group and also the need for a transfusion was lower in the ERAS Group. In this group, the need for infusing less than 5000 ml of fluid therapy was statistically higher. Use of vasopressors did not show statistically significant differences between both groups. The total length of stay was statistically significant shorter in the ERAS group. No differences in 30-days mortality were found (Table 2).

Table 1 Demographic characteristics (N. 67)

Characteristics		N.	%
Gender	Female	33	49.3
Age*		58.2	12.5
Diagnostics			
	Pancreatic Cancer	48	71.6

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Table Continued...

Characteristics	N.	%
Intraductal Papillary Mucinous Neoplasm (IPMN)	6	9
Duodenal adenocarcinoma	4	6
Other	4	6
Neuroendocrine Tumor	2	3
Serous Cysts	1	1.5
Solid Neoplasm	1	1.5
Distal cholangiocarcinoma	1	1.5
Postoperative Pancreatic fistula (POPF)		
No POPF	56	83.6
Grade A	3	4.5
Grade B	4	6
Grade C	4	6
Delayed Gastric Emptying (DGE)		
No DGE	59	88.1
Grade A	3	4.5
Grade B	5	7.5
Grade C	0	0
Fluid Therapy		
Less 2500 ml	18	26.9
2500 -5000 ml	33	49.3
5000-7500 ml	13	19.4
More 7500 ml	3	4.5
Blood Loss		
Less 300 ml	24	35.8
300-600 ml	25	37.3
600-900 ml	6	9
More 900 ml	12	17.9
Vasopressors Use	33	49.3
Transfusion	10	14.9
Length of stay ICU (days) †	1	(1-2)
Length of stay (días)†	8	(6-14)
Mortality 30 days	6	9

*Media (ED) †Median (IQR)

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Table 2 Outcome according No-ERAS Group and ERAS group (N.67).

Characteristics n. (%)	No-ERAS Group (n.21)	ERAS Group (n.46)	OR (IC95%)	P*
Postoperative Pancreatic Fistula (POPF)				0.556
No POPF	19 (90.4)	37 (80.4)	1	
Grade A	1 (4.8)	2 (4.3)	0.98 (0.19-5.07)	
Grade B	0 (0)	4 (8.7)	-	
Grade C	1 (4.8)	3 (6.5)	0.74 (0.13-4.18)	
Delayed Gastric Emptying (DGE)				0.009
No DGE	15 (71.4)	44 (95.7)	1	
Grade A	3 (14.3)	0 (0)	3.93 (2.54-6.08)	
Grade B	3 (14.3)	2 (4.3)	2.36 (1.02-5.45)	
Grade C	0(0)	0(0)	-	
Vasopressors Use	12 (57.1)	21 (45.7)	1.58 (0.56-4.49)	0.383
Transfusion	8 (38.1)	2 (4.3)	13.53 (2.55-71.80)	<0.001
Fluid Therapy				0.001
Less 2500 ml	2 (9.5)	16 (34.8)	1	
2500-5000 ml	8 (38.1)	25 (54.3)	2.18 (0.51-9.2)	
5000-7500 ml	8 (38.1)	5 (10.9)	5.54 (1.39-21.92)	
More 7500 ml	3 (14.3)	0 (0)	9.00(2.44-33.24)	
Blood Loss				0.001
Less 300 ml	3 (14.3)	21(45.7)	1	
300-600 ml	6 (28.6)	19 (41.3)	1.92(0.54-6.82)	
600-900 ml	3 (14.3)	3 (6.5)	4.00(1.06-15.07)	
More 900 ml	9 (42.9)	3 (6.5)	6.00(1.98-18.16)	
Length of Stay ICU (days) †	1 (1-6)	1 (1-2)	-	0.329‡
Length of Stay (days) †	14 (8-20)	7 (5-12)	-	<0.001‡
Mortality 30 days	2 (9.5)	4 (8.7)	1.15 (0.18-6.56)	0.912

IC95%, confidence interval 95% OR, odds ratio

*Chi square Pearson †Median (IQR) ‡ U Mann Whitney

Discussion

One of the most challenges points during surgery for the anesthesiologist is fluid therapy, which must be guided by algorithms aimed at physiological objectives, knowing that hyper or hypovolemic states increase the risk of complications.[9–11] Moreover, fluid therapy should be administered when the patient is a responder to volume according to the Frank-Starling curve to achieve adequate tissue perfusion.[12–14] Navarro et al.[15] recommend the use of protocols and fluid therapy directed by goals based on the measurement of dynamic variables (such as stroke volume variation: VVS, pulse pressure variation: PPV) in major surgeries.[15,16] Since the introduction of the ERAS guidelines, their multimodal approach and strategies are meant to reduce the length of stay, morbidity and improve the functional capacity of the patient.[17] These strategies from the anesthetic point of view are aimed at better control of pain which leads to an early mobilization; better fluid control, which starts from the preoperative period with shorter fasting times for liquids and decreases the net fluid balances.[18] This is how the patient included in enhanced recovery programs have faster hospital discharges, less medical complications, and lower hospital costs, compared with the standard perioperative treatment groups.[19,20]

Recently, the administration of intravenous fluids in the perioperative period has received greater attention due to its impact on patient recovery.[21] Several studies have suggested that the adequate and restrictive administration of intravenous fluids reduces the complications, recovery time and hospital stay of patients undergoing major gastrointestinal surgery; while on the contrary, the liberal administration of fluids is associated with an increased mortality and the appearance of complications such as pancreatic fistula, whose incidence in the literature is reported between 10 to

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40%.[11,21,22] However, Chen et al.[23] found that there is a small number of studies to draw conclusions about this subject.[23] DP is one of the most challenging intra-abdominal operations. However, even the most uneventful DP can be associated with a POPF.[24] The exact pathophysiological mechanism explaining the appearance of the pancreatic fistula is unclear. It has been postulated that excessive administration of intravenous fluids in the perioperative period may cause edema in the parenchyma of the gland and in general of the entire gastrointestinal tract that could alter the healing of the pancreatic anastomosis. In addition, this predisposes to suture dehiscence due to increased intestinal pressure of the submucosa, decreased oxygenation and decreased mesenteric blood flow and intramural acidosis.[25] Wang et al.[26] concluded in their studies that complications in pancreatic anastomosis were greater in patients with high intraoperative fluid volumes (≥8.2ml/kg/h) (P=0.035).[26] On the other hand, Kulemann et al.[11] in a retrospective study concluded that a duration of surgery greater than 420 minutes predisposes the patient to receive a greater amount of intravenous fluids and therefore to greater complications in the postoperative period (P <0.001) with the appearance of pancreatic fistula B/C (P <0.005).[11]

Multiple strategies have been developed trying to reduce the incidence of POPF after DP, those include modifications in the technique used for the pancreatic stump anastomosis, such as end-to-side pancreatojejunostomy (PJ),[27] pancreaticogastrostomy (PG),[28] dunking PJ,[29,30] or pancreatic duct occlusion,[29,30] among others, also associated with or without the use of a plastic stent in the pancreatic duct.[31] However, the evidence to favour one technique over the others to reduce the incidence of POPF after PD is not conclusive.[32–35] In the present study, there was no difference in the incidence of POPF according to the chosen technique for the pancreatic reconstruction. However, a higher incidence of postoperative upper gastrointestinal bleeding was observed in PG, as shown by other reports.[36] In our study, patients who presented postoperative pancreatic fistula were mostly type B or C and were part of the ERAS group (P=0.556). However, it was found that the implementation of the ERAS protocol in this group of patients was associated with less DGE, less intraoperative bleeding, the need for transfusions and less hospital stay. Goal-directed fluid therapy is the most accepted way to guide the perioperative fluid administration, reducing the risk of complications and decrease hospital stay.[37] Sulzer et al.[38] reviewed the Systolic Volume Variability (SVV) during DP, and found that patients with SVV ≥12% in the removal phase of the procedure, had lower rates of pancreatic postoperative leaks than patients with SVV <12%. Despite this finding was not statistically significant, it is highlighted by the researchers that goal-directed fluid therapy can contribute to decrease the rate of pancreatic fistula and other secondary outcomes such as DGE.[38] Our hospital protocol for fluid therapy included SVV <13%; however, this did not show statistical differences with respect to POPF development, although it did for DGE.

Our study has its own limitations due to the retrospective observational and single centre design method. The number of patients its nearly twice as many in the ERAS-group compare to the No-ERAS group and the total incidence of POPF is very low which make statistical analysis difficult. Also, the comorbidities of the patients were not taken into account and a small number of patients analyzed. In conclusion, the implementation in ERAS protocol showed a decreased in intraoperative blood loss, intravenous fluid therapy, need for transfusion, DGE and total length of hospital stay in our centre; nevertheless, intraoperative fluid restriction in DP did not show to affect significantly the incidence POPF.

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Conflicts of interest

Author declares that there is no conflict of interest.

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