

Research Article

Preliminary Data on Tolerability and Feasibility of Specific Stepwise Diet Protocols in Patients Undergoing Pancreaticoduodenectomy

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Abstract

Background: The number of patients undergoing Pancreaticoduodenectomy (PD) has increased dramatically in the last decades and at the same time, outcomes have improved. Among the postoperative complications Delayed Gastric Emptying (DGE) is one of the most troublesome. Enhanced Recovery After Surgery (ERAS) pathway is an interdisciplinary model, aimed to safely manage post-operative recovery being the possibility to early resume an oral feeding a key concept.

Aim: The aim of the present study is to assess the feasibility and tolerability of a specific diet protocol following PD.

Patients and methods: 27 consecutive patients, who underwent a PD at the Campus Bio-Medico University of Rome, between January 2014 and December 2015, were enrolled. All patients started an early oral feeding on postoperative day 2 with a specific diet protocol characterized by a progressively increasing amount of calories, from 405 kcal to a maximum of 1770 kcal (DCP I-VI).

Results: All patients started an early oral feeding on postoperative day 2. 17 of 27 patients (63%) were able to complete the full diet protocol (from DCP II to DCP VI) without any interruption (fully compliant patients), whereas 5 patients (18%), completed the diet protocol in 9±2 days (partially compliant patients). Five patients (18%) developed a DGE. On the day of discharge, 4 out of 27 patients (15%) received an oral nutritional supplement. Mean length of hospital stay was 14.2±6.2 days: 11.4±4 days in fully compliant patients, 17.2±3 days in partially compliant patients and 20.8±8.8 days in non-compliant patients. Fully compliant patients showed a mean length of hospital stay significantly shorter than partially compliant and non-compliant patients ($p < 0.01$).

Conclusion: The results coming from this pilot study show that early oral feeding in our series of patients undergoing PD is feasible, safe and well tolerated. Further studies on a larger series of patients are needed in order to confirm our preliminary findings and to assess the impact of early oral feeding compliance on the long-term outcome.

Keywords: Pancreatic Oduodenectomy; Delayed Gastric Emptying; Enhanced Recovery After Surgery; Diet; Protocols

Introduction

The number of patients undergoing Pancreatic Oduodenec-

omy (PD) has increased dramatically in the last decades and at the same time, outcomes has improved. Postoperative mortality rates have significantly decreased thanks to centralization policies advances in surgical technique, perioperative care and multidisciplinary management of complications[1]. However, even in high-

volume centers such as institutions performing more than 15-20 pancreatic resections per year, patients still experience significant postoperative morbidity and full recovery after surgery takes longer than expected[2]. Among the postoperative complications the most prevalent are the pancreatic fistula, the intra-abdominal complications, such as abscess, and the syndrome of Delayed Gastric Emptying (DGE)[2].

DGE is one of the most troublesome postoperative complications after PD and occurs in nearly 30% of the patients. The available definition of DGE is based on the inability to return to a standard diet by the end of the first postoperative week and includes prolonged nasogastric intubation of the patient[3]. Moreover, the presence of DGE has been related to prolonged hospital stay, increasing costs and impaired quality of life. The relationship between postoperative complications and the occurrence of DGE has not been fully understood yet, although local inflammation or the presence of abscesses was hypothesized to be the main causes of the delayed gastric motility[4]. Notwithstanding that DGE is mostly related to postoperative complications, a subgroup of patients can develop a primary or pure DGE in the absence of other complications[2].

Enhanced Recovery after Surgery (ERAS) is an interdisciplinary multimodal concept designed to accelerate postoperative recovery: morbidity is reduced and patients recovery is improved by decreasing surgical stress, obtaining good pain control, early resuming of oral feeding and mobilization; consequently the Length-Of-Stay In Hospital (LOSH) and costs are significantly reduced[5]. It has been demonstrated that early postoperative oral feeding may be an additional tool to improve gastric emptying. While fasting impairs the peristaltic activity of the stomach and small intestine, the fed state seems to be characterized by more effective peristaltic waves. In this light, a previous study showed that a fast-track program following PD (oral feeding on the day 4 after surgery) improves gastric emptying and reduces postoperative stay[6]. Although growing evidence suggests an implementation of the fast track program, allowing patients to resume oral feeding on day 2 after surgery, to date, there are only few available data concerning the compliance to early oral feeding and the rate of patients achieving dietary goals after PD[7]. Therefore, the aim of the present study is to assess the feasibility and tolerability of a specific diet protocol following PD.

Patients and method

From January 2014 and December 2015, 27 consecutive patients underwent the protocol of early oral feeding following PD as shown in (Table 1).

Postoperative day	II	III	IV	V	VI
Kcal	405	640	1200	1580	1770
Proteins (g)	9	36	61	72	84
Lipids (g)	2	6	29	42	45
CHO (g)	90	103	185	241	274
Fibers (g)	2	3	6	14	18

Table 1: Diet protocols.

Diet Protocol: All patients started an early oral feeding on postoperative day 2 with a specific stepwise diet protocol characterized by a progressively increasing amount of calories, from 405 kcal to a maximum of 1770 kcal namely DCP II to DCP VI (Table 1). The protocol also provided a gradual increase of lipids, proteins, fibers and lactose. Compliance to diet protocol was monitored by a food diary recording system, administered by an expert dietitian. The total amount of calories of each diary was calculated by a dedicated software (Sapermangiare.mobi). Patients were allowed to switch the following diet protocols if they were able to eat at least 75% of the prefixed calories.

Surgical procedure: Incidence of postoperative complications, such as DGE (according to the definition proposed in a previous study[3]), abdominal abscess and pancreatic fistula (according to definition of the International Study Group on Pancreatic Fistula (ISGPF)[8]), was monitored. The occurrence of DGE was defined as primary, in the absence of other complications, and secondary, when associated with abdominal abscess, pancreatic fistula or other postoperative complications. In the postoperative setting, the nasogastric tube was removed on day 1 after PD and an early mobilization program was applied in all patients. Data were collected prospectively in a database and analyzed retrospectively. Surgery was performed by the same surgeon, using a right subcostal incision extended to the left side. When possible, a pylorus-preserving pancreaticoduodenectomy was performed, with standard lymphadenectomy. During surgery a biliary culture was collected for microbiological examination. The reconstructive phase provided pancreatico-jejunostomy, biliary-jejunostomy and, finally, an anti-colic duodenal-jejunostomy (or gastro-jejunostomy in case of Whipple's procedure). Two surgical drains were placed: the right one near the biliary-jejunostomy and pancreatico-jejunostomy and the left one near the duodenal- and front of the pancreatico-jejunostomy. A nasogastric tube was routinely placed. Analgesia was obtained by morphine (10 mg) and Ketorolac (60 mg), whether not contraindicated. No prokinetic agents were administered.

Statistical analysis: Values are expressed as means ± SEM. The

unpaired 't' test was used to compare differences between groups. A p value < 0.05 was considered to be significant.

Results

Demographics and intra-operative parameters

Demographic and clinical characteristics of patients who underwent PD, included in the present analysis, are displayed in (Table 2)

Demographic characteristics	Study Group (n=27)
Mean age (years ±DS)	65 ±10
Female number (percentage)	13 (48%)
Diagnosis	
Pancreatic cancer	17
Periampullary cancer	8
Chronic pancreatitis	2
Clinical characteristics	
Preoperative jaundice	6 (22%)
Preoperative diabetes	3 (11%)
BMI (mean±DS)	24±3.9
n (%) of patients with preoperative weight loss >5%	11 (40%)

Table 2: Demographic and Clinical characteristics of patient.

A Pylorus-Preserving PD (PPPD) was performed in 17 out of 27 patients (63%), whereas Whipple procedure was performed in 10 patients (37%). The average duration of surgery was 384 minutes and the median intraoperative blood loss was approximately 350 ml.

Compliance to stepwise oral feeding protocol

In 27 out of 27 patients (100%) the nasogastric tube was removed on the first postoperative day. All patients were allowed to take clear fluids on day 1 and they were able to resume oral feeding on the second postoperative day. Seventeen out of 27 patients (63%) were able to complete the entire diet protocol (from DCP II to DCP VI) without any interruption (fully compliant patients), whereas 5 patients (18%), completed the diet protocol in 9±2 days (partially compliant patients). Five patients (18%) developed a DGE and started therefore an enteral nutrition (not compliant patients). On the day of discharge, 4 out of 27 patients (15%) received an oral nutritional supplement added to their oral feeding, in order to achieve 95% of prescribed calories. Patients characteristics according to compliance to diet protocol are shown in (Table 3).

	Fully compliant	Partially compliant	Non compliant
n	17	5	5
Age (Mean± SD)	64±10	70±12	69±7
BMI (Mean± SD)	24±4	26±1	24±4
Preoperative diabetes n (%)	2 (13%)	0 (0%)	1 (25%)
Preoperative weight loss >5%	4 (23%)	2 (40%)	5 (100%)

Table 3: Characteristics of the patients according to compliance to diet protocol.

Clinical outcome

Overall mean length of hospital stay was 14.2±6.2 days: 11.4±4 days in fully compliant patients, 17.2±3 days in partially compliant patients and 20.8±8.8 days in non compliant patients. Fully compliant patients showed a mean length of hospital stay significantly shorter than partially compliant and non-compliant patients (p<0.01). The occurrence of postoperative complications is displayed in (Table 4). The overall mortality rate was 3%. The occurrence of secondary DGE was related to the presence of one major surgery complication in all cases. None of our patients presented a primary DGE.

	Study Group (n= 27)
Overall mortality	1 (3%)
Morbidity	18 (66%)
Relaparotomy (deaths excluded)	1 (3%)
Percutaneous drainage (deaths and relaparotomy excluded)	5 (18%)
Access	10 (37%)
Pancreatic Fistula	
Type A	10
Type B	2
Type C	1
DGE	
Total	5/27 (19%)
Primary	0
Secondary	5/5 (100%)

Table 4: Occurrence of postoperative complications.

Discussion

ERAS (Enhanced Recovery After Surgery) program represents an interdisciplinary model, designed to safely manage postoperative recovery with a positive modulation of stress response[3]. A key component of ERAS protocol is the possibility to early resume an oral feeding after surgery, being pre or postoperative artificial nutrition not recommended[3,9-11]. Perioperative nutritional support in pancreatic cancer patients is still under debate. Despite in the ERAS pathway patients are allowed to resume oral feeding soon after PD, it should be also recommended to strictly monitor their compliance [12]. Preliminary results from this pilot study show that early oral feeding with a stepwise protocol is feasible and well tolerated by the majority of patients undergoing PD. In our group of patients, a clear fluids diet was prescribed from the first postoperative day and a stepwise diet protocol was administered thereafter, with a compliance of 90%. The high compliance rate, reported in this study, is in line with previous articles[4,7] and could be explained with the customized preoperative counseling that is routinely performed in our hospital. Indeed, it has been demonstrated that preoperative counseling contributes to alleviate fear and anxiety; moreover it is a good chance to communicate the importance of achieving daily targets before and after surgery[10]. In addition, our patients underwent nutritional counseling by an expert dietitian who explained each step of postoperative oral feeding protocol in detail. This approach was also enhanced by daily counseling during hospitalization. Compliance to early oral feeding was significantly associated with an early discharge from the hospital, thus representing a sign of total functional recovery.

A large body of evidence supports the pivotal role of nutritional and metabolic alterations before surgery in determining the incidence of adverse events and the impairment of surgery-related outcome[13]. The nutritional interventions made in the perioperative period can be crucial in improving the clinical outcome of patients with cancer [14], indeed malnutrition is a preventable and possibly treatable condition[15]. As far as concern the caloric requirement, it is well known that eating enough to meet nutritional targets is crucial in order to prevent and/or treat malnutrition: weight loss is frequently observed in cancer patients, even in an early disease stage and, when present, it is associated with a negative clinical outcome[14,16]. Therefore, it appears mandatory to ensure the achievement of caloric requirements in these patients, either with an oral diet or with the use of oral nutritional supplements, when required as part of the nutritional and metabolic support of the patient's cancer journey[17].

The presence of postoperative complications is the most significant risk factor for DGE, as supported by a recent evidence showing a significant correlation between the incidence of DGE and the presence of pancreatic fistulas [2,3]. The mechanism under-

lying postoperative gastro paresis, gastric stasis and DGE are still poorly understood[5,6]. Treatment with prokinetic drugs such as erythromycin, a motilin receptor agonist, was shown to reduce the incidence of DGE, supporting the hypothesis that duodenal resection, and postoperative decrease in plasma motilin levels may be possible triggers of DGE[2,18]. Even if the occurrence of DGE is mostly related to other postoperative complications, a subset of patients can develop a primary or pure DGE[2]. In our series of patients, DGE was developed only in the presence of other complications such as a pancreatic fistula, while no primary DGE was observed. The possible major limitations of the present study are represented by the small sample size, the lack of a control group and the absence of a long-term clinical follow-up.

In conclusion, our results coming from this pilot study show that early oral feeding in our small series of patients undergoing PD is feasible, safe and well tolerated. The amount of oral intake needs to be strictly monitored; moreover, it must be emphasized that selected subgroups of patients undergoing PD could benefit from an artificial nutritional support.

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