1 2	Biliopancreatic diversion with duodenal switch in the elderly: Long-term results of a matched-control study
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14	<i>Running title:</i> BPD-DS in the elderly
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31 ABSTRACT

32 **Introduction:** BPD-DS is one of the most effective surgical approaches for the treatment 33 of severe obesity. **Objective:** To compare perioperative complications and long-term 34 results of open BPD-DS in elderly versus younger patients. Methods: All patients aged 35 60 years and above who underwent a primary open BPD-DS in our center were selected 36 (n=105). Patients were matched 1:1 for sex, BMI, the presence of Type 2 diabetes 37 (T2DM) and year of surgery with a group of younger patients (aged \leq 55 years). **Results:** 38 The mean age of the patients was 62.3 ± 2.0 vs. 40.4 ± 7.0 years (p ≤ 0.0001). Initial BMI and prevalence of T2DM were similar in both groups, at 50.9 kg/m² and 57%. 39 40 respectively. Mean operative time (178.6±46.7 vs. 162.5±39.9 min., p=0.01), hospital 41 stay (10.2 \pm 8.3 vs. 6.3 \pm 1.5 days, p=0.0001) and blood loss (593 \pm 484 vs. 474 \pm 241ml, 42 p=0.05) were significantly higher in elderly patients. No difference in 30-days mortality 43 rate was observed (0.9% in each group). There was no significant difference in major 44 complication rate (16.2% vs. 8.6%, p=0.09). At a mean follow-up of 7.1±4.1 years, excess weight loss (67.6 \pm 19.2% vs. 72.7 \pm 20.7%, p=0.06) and BMI (32.2 \pm 5.7kg/m² vs. 45 30.8 ± 6.6 kg/m², p=0.15) were not significantly different. No significant difference was 46 47 observed between the two groups for the resolution of T2DM (p=0.53) and obstructive 48 sleep apnea (p=0.44). Conclusion: Open BPD-DS is associated with similar long-term 49 benefits in elderly and younger patients, in terms of weight loss and resolution or 50 improvement of obesity-related comorbidities. Perioperative complications might be 51 more frequent in the elderly population, but this was not associated with increased 52 mortality.

Keywords: Bariatric surgery, Biliopancreatic diversion, Duodenal switch, long-term
 results, Elderly

55 INTRODUCTION

56 Epidemiological studies demonstrated that obesity rates have progressively increased 57 over the past decades [1-4]. More specifically, the prevalence of severe obesity increased 58 by 225% in Canada (0.4% in 1990 to 1.3% in 2003) [1]. Bariatric surgery is still the only 59 treatment for severe obesity to offer significant and durable weight loss [5]. 60 Biliopancreatic diversion with duodenal switch (BPD-DS) is one of the most effective surgical approaches for the treatment of severe obesity in terms of weight loss and 61 62 resolution of comorbidities [6, 7]. BPD-DS was developed at the Ouebec Heart and Lung 63 Institute (IUCPO) in the early 1990s and became the primary approach for most severely obese patients. This procedure combines restrictive and malabsorptive mechanisms by 64 creating a 250-cm³ sleeve gastrectomy (SG), while the duodenum is transected about 4 65 66 cm distal to the pylorus and anastomosed to a 250-cm alimentary limb, with a 100-cm 67 common channel [6, 8].

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69 The effect and long-term outcomes of bariatric surgery procedures in various sub-70 populations of severely obese patients have been reported extensively in the past years [5, 71 6, 8-15]. However, the risks and benefits of these operations in elderly patients are still 72 debated [16-18]. Indeed, multiple studies [19-37], two recent reviews [16, 18] and one 73 meta-analysis [17] have examined this question and no consensus could be reached. One 74 review concluded that bariatric surgery is safe and effective in elderly patients [16], while 75 the other concluded that bariatric surgery in this population is associated with higher 76 perioperative complications, and lower weight loss and comorbidities resolution [18]. Of the studies available, most were retrospective, and included small patient numbers and 77

78	no control group [17]. Furthermore, long-term data in the elderly population are still very
79	limited and very few studies are available regarding the effectiveness of BPD-DS
80	specifically in elderly patients [17].
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82	Considering that the prevalence of severe obesity increased [1] and that the population is

ageing [18], more data are needed on the safety and effectiveness of BPD-DS in elderly

84 patients. Our objective was to compare perioperative complications and long-term results

85 of open BPD-DS in elderly versus younger patients. We tested the hypothesis that open

86 BPD-DS is associated with similar long-term benefits in elderly compared to younger

87 patients, in terms of excess weight loss and resolution of obesity-related comorbidities.

88 **RESEARCH DESIGN AND METHODS**

89 Patients

90 The present study took place at a single university-affiliated tertiary care center. All 91 patients aged 60 years and above who underwent a primary open BPD-DS with standard 92 intestinal measures (250-cm alimentary limb and 100-cm common channel) from 93 November 1992 to September 2011 were included in the study (n=105). These patients 94 were individually matched (1:1) for sex, BMI, the presence of T2DM and the year of surgery with a group of younger patients (aged <55 years, n=105). Data were obtained 95 96 from a prospectively maintained database. The database and the medical record were 97 reviewed for each patient. In the present study, preoperative data obtained for each 98 patient included age, gender, weight, height, body mass index (BMI), comorbidities and 99 medication use. The indications for surgery followed the National Institutes of Health 100 guidelines [38], except for age in the elderly subgroup. The decision regarding surgery 101 was made in collaboration with the bariatric multidisciplinary team (surgeon, nutritionist, 102 social worker and bariatric nurse) and the patient. All patients were informed about the 103 risk and benefits of the BPD-DS and they participated in a support group before surgery. 104 This study received approval from the Ethics Committee of our institution.

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106 Surgical technique

Patients received intravenous antibiotics and subcutaneous heparin 2 hours before
surgery. Pneumatic compression devices were used during surgery and until ambulation.
The surgical technique consisted in open BPD-DS with a 250-cm alimentary limb and a
100-cm common channel, as previously described [6]. Sleeve gastrectomy starting 7 cm

proximal to the pylorus was performed using a 52F bougie for calibration. Routinecholecystectomy and appendectomy were performed.

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114 Perioperative period, follow-up and outcome definitions

115 Regular subcutaneous heparin was given for the first postoperative day and then switched 116 to low-molecular-weight heparin. Patients were discharged with the same regimen for 3 117 weeks when they were tolerating a soft diet. Vitamin and mineral supplementation 118 (ferrous sulfate 300mg, vitamin D 50 000IU, vitamin A 20 000IU, calcium carbonate 119 500-1000mg, and a multivitamin complex) were started within the first month after 120 surgery and these supplements were adjusted during follow-up according to plasma 121 nutritional markers. Nutritional deficiencies were immediately corrected using standardized protocols. Patients also received recommendations to consume a high-122 123 protein diet. Perioperative data such as operative time, duration of hospital stay, blood 124 loss, mortality rate as well as major and minor complications within 30 and 90 days 125 postoperatively were recorded. The hospital stay was defined as the number of days from 126 operation to hospital discharge. The reoperation rate within 10 days was also calculated.

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Follow-up data were gathered at 3, 6, 9 and 12 months postoperatively and yearly thereafter. Clinical biochemistry values included a complete blood count, liver enzymes, albumin, transferrin, iron, ferritin, calcium, parathyroid hormone, vitamin A, vitamin B12 and folic acid. Bariatric nurses remained in contact with these patients and their primary care physician, making a yearly average of 6 phone calls per patient [6]. Information regarding late complications and hospitalizations were documented in the database. To 134 verify the collected information, an auto-administered written questionnaire was sent to 135 each patient every 5 years. These questionnaires included questions regarding overall and 136 weight loss satisfaction, quality of life, side-effects, complications and evolution of 137 comorbidities. To evaluate the nutritional condition of the two groups, we compared 138 nutritional laboratory values after 5 years of follow-up with those obtained prior to 139 surgery. Percentage of excess weight loss (%EWL), postoperative BMI and percentage of 140 total weight loss (%TWL) after a mean follow-up of 7.1±4.1 years were calculated for all 141 patients. The %EWL was calculated using these variables: total preoperative weight, postoperative weight and ideal body weight (IBW) for an ideal BMI of 23kg/m² as 142 143 previously used [8]. Resolution of comorbidities (T2DM, hypertension and sleep apnea) 144 was also recorded. The resolution or improvement of T2DM, hypertension and sleep 145 apnea was evaluated by surgeons during follow-up on the basis of clinical parameters, 146 laboratory data and the reduction or discontinuation of medical therapy. The resolution of 147 T2DM was defined as a normal glycosylated hemoglobin (HbA1c) (<6%) or normal 148 fasting blood glucose (<5.6mmol/L) and absence of anti-diabetic medication use. The 149 resolution of hypertension was defined as normal resting systolic and diastolic blood pressure (BP<120/80 mm Hg) as well as absence of anti-hypertensive medication use. 150 151 The resolution of sleep apnea was defined as cessation of the use of continuous positive 152 airway pressure (CPAP). T2DM, hypertension and sleep apnea were improved when 153 patients had improved clinical parameters and/or medication dose was decreased.

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157 Statistical analysis

Student's t-tests were performed to compare continuous variables between patients aged 158 60 years or older and controls (patients aged <55 years). Chi-square tests or Fisher's 159 160 exact tests were performed to compare categorical variables, as appropriate. Repeated-161 measures analysis of variance was used to examine the effect of group (elderly patients 162 (age \leq 55 years) versus younger patients (age \geq 60 years)) and time (before-BPD-DS and 163 5 years post-BPD-DS) as well as the time-by-group interaction for mean levels of 164 albumin, calcium, hemoglobin and iron. Non-normally distributed variables were log- or 165 boxcox-transformed. When variables could not be normalized, Wilcoxon tests were computed to compare continuous variables. Results are reported as mean \pm standard 166 167 deviation for continuous variables or percentage for categorical variables comparing 168 elderly to younger patients. The results were considered statistically significant with p 169 values ≤ 0.05 . All statistical analyses were performed with JMP software (SAS Institute 170 Inc, Cary, NC, U.S.A.).

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177 **RESULTS**

178 **Preoperative characteristics**

179 Preoperative demographic characteristics of the two groups are shown in **Table 1**. The 180 mean age of the patients at the time of surgery was 62.3 ± 2.0 versus 40.4 ± 7.0 years 181 ($p \le 0.0001$). As expected from our matching procedure, preoperative BMI, gender and % 182 of T2DM were similar in both groups. In the elderly group, 36.7% (n=22) of diabetic 183 patients were on insulin treatment compared to 20% (n=12) in the younger group 184 (p=0.04) (data not shown). Hypertension, cardiovascular disease, dyslipidemia and 185 obstructive sleep apnea affected 72%, 20%, 38% and 64% of all patients respectively. 186 Patients aged 60 years and above had a significantly higher mean number of 187 comorbidities (p=0.002) and used a significantly higher mean number of preoperative 188 daily medications $(5.4\pm2.9 \text{ versus } 3.9\pm3.4, p=0.0001, \text{ data not shown})$ compared to 189 younger patients.

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191 *Perioperative data, early mortality and early complications* (\leq 30 *days*)

192 Including all patients, mean postoperative hospital stay was 8.2 ± 6.1 days and mean 193 operative time was 170.5 ± 44.1 minutes (**Table 2**). Mean operative time, hospital stay and 194 blood loss were all slightly but significantly higher in the elderly group ($p \le 0.05$, for all). 195 The rate of reoperation during the first 10 postoperative days was similar between the two 196 groups. One death (0.9%) occurred within 30 days in each group (a 30-year-old patient 197 died from a pulmonary embolism 12 days after surgery and a 70-year-old patient died 198 from multiple organ failure. At 90-days, mortality was 0.9% (1/105) in the younger group 199 versus 1.9% (2/105) in the elderly group (p=0.55).

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201 Major complications in first 30 postoperative days are shown in **Table 3**. Major 202 complications occurred in 12.4% of all patients. A trend was observed for an increased 203 rate in total major 30-days complications in elderly patients compared to younger ones 204 (16.2% versus 8.6%, p=0.09). The rate of digestive leak, abdominal abscess, pancreatitis, 205 pneumonia, hemorrhage, pulmonary embolism, intestinal obstruction and stenosis was 206 similar between the two groups. Table 4 shows minor complications in first 30 207 postoperative days. There was no significant difference between the two groups for total 208 minor complication rate (13.3% versus 9.5%, p=0.40).

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210 Long-term results: weight loss, general satisfaction, resolution of comorbidities, 211 complications, nutritional outcomes and long-term mortality

212 The mean follow-up time was similar between the two groups $(7.2\pm4.2 \text{ years in the})$ 213 elderly group versus 7.1 \pm 4.1 years in the younger group, p=0.89). The percentage of 214 follow-up was 97% in elderly patients (102/105) and 99% in younger patients (104/105). 215 Figure 1A shows mean percentage of initial excess weight loss (%EWL) for the two 216 groups after 6, 12, 24, 36, 48 and 60 months of follow-up. The mean %EWL was 217 significantly higher in younger patients after 6, 12, 24, 36 and 48 months of follow-up 218 $(p \le 0.05 \text{ for all}, Figure 1A)$. However, the difference in %EWL between the two groups 219 was not significant after 60 months of follow-up (p=0.22). In both groups, weight loss 220 remained relatively stable over the years (Figure 1A). After a mean follow-up of 7.1±4.1 221 years, there was no significant difference between the two groups for %EWL 222 (67.6±19.2%) versus 72.7±20.7%, p=0.06) and BMI $(32.2\pm5.7 \text{kg/m}^2)$ versus

30.8±6.6kg/m², p=0.15) (Figure 1B and D). The %TWL was significantly higher in 223 224 younger compared to elderly patients (p=0.05) (Figure 1C). The percentage of successful 225 weight loss which is defined as an average weight loss >50% of initial excess weight was 226 similar in both groups (82.9% in elderly patients versus 85.7% in younger patients, 227 p=0.58, data not shown). After a mean follow-up of 7.1 years, 0.9% (1/105) of elderly 228 patients and 2.9% (3/105) of younger patients had lost less than 25% of their initial 229 excess weight (p=0.37, data not shown). To evaluate overall satisfaction of patients 230 regarding surgery and weight loss, an auto-administered questionnaire was sent in 2011. 231 Of the 210 patients, 108 patients (51%) correctly filled the questionnaire. According to 232 this questionnaire, 85.7% (54/63) of the elderly group were satisfied (score 4 or 5 on a 1 233 to 5 Likert-scale) with their weight loss compared to 97.8% (45/46) of the younger group 234 (p=0.10) (data not shown). Only 2 older patients (3.2%) were unsatisfied (score 1) with 235 their weight loss. In both groups, no revision surgery was required for insufficient weight 236 loss.

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238 The questionnaire also included questions regarding frequency of stools, prevalence of 239 diarrhea, bloating and flatulence/odor problems. The mean number of stools per day was 240 2.8 ± 1.5 in elderly patients and 3.2 ± 1.6 in younger patients (p=0.17) (data not shown). 241 The number of stools per day was not considered as a significant problem in most of the 242 elderly (92%) as well as younger (95%) patients. The presence of abdominal bloating 243 (more than once a week) was found in 39% of the elderly group compared to 44% of the 244 younger group (p=0.50) (data not shown). Flatulence or odors were considered as a major 245 problem in 30% of the elderly group and in 33% of the younger group (p=0.67) (data not

- shown). In both groups, no reoperation was specifically performed to address number ofstools per day or frequency of flatulence/odor problems.
- 248

249 Figure 2 shows the resolution of obesity-related comorbidities among younger and 250 elderly patients after a mean follow-up of 7.1±4.1 years. No significant difference was 251 observed between the two groups for the resolution of T2DM (p=0.53) (Figure 2A). In 252 the elderly group, T2DM was cured in 83.3% (50/60), improved in 8.3% (5/60) and 253 unchanged in 1.7% (1/60). In the younger group, T2DM was resolved in 91.7% (55/60), 254 improved in 3.3% (2/60) and unchanged in 1.7% (1/60). In both groups, a significant 255 decrease in HbA1c was observed at the last follow-up (the most recent postoperative 256 value) compared to levels obtained prior to surgery (Elderly patients: 6.8±1.2% versus 257 5.2±0.7%, p<0.0001, n=48; Younger patients: 6.8±1.9% versus 5.0±0.6%, p<0.0001, 258 n=43) (data not shown). A significant difference between the younger and elderly groups 259 was observed for hypertension resolution (Figure 2B). Indeed, hypertension was resolved 260 in 41.1% (35/85), improved in 41.1% (35/85) and unchanged in 7.1% (6/85) in the older 261 group compared to 66.7% (44/66), 13.6% (9/66) and 13.6% (9/66) respectively in the 262 younger group (p=0.008). The resolution of obstructive sleep apnea was similar between 263 the two groups (p=0.44) (Figure 2C). Sleep apnea was resolved in 72.9% (43/59) and 264 improved in 10.2% (6/59) in younger patients compared to 77.3% (58/75) and 12.0% 265 (9/75) respectively in elderly patients. Of the 75 older patients treated for sleep apnea 266 before BPD-DS, only 2 patients (2.7%) required treatment after surgery.

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269 Changes in nutritional parameters

270 To evaluate the nutritional condition of the two groups, we compared nutritional markers 271 after 5 years of follow-up with those obtained prior to surgery, when both were available 272 (Figure 3). No significant difference was observed between the two groups for mean 273 level of albumin measured prior to and 5 years after BPD-DS (Group effect, p=0.79) 274 (Figure 3A). In both groups, mean albumin level was slightly decreased after 5 years of 275 follow-up compared to that obtained prior to surgery (Time effect, p=0.02). Taking into 276 consideration the most recent postoperative albumin level, most patients remained within 277 the normal limit (albumin level >35g/L). Only 18.1% of elderly patients and 5.7% of 278 younger patients were below normal (albumin level \geq 30 but <34.9g/L). The percentage of 279 severe hypoalbuminemia (<30 g/L) was very low and similar in both groups prior to 280 surgery and at the last follow-up (most recent nutritional markers obtained after the 281 surgery) [Elderly patients: 0.9% (preoperatively) versus 0% (postoperatively), n=105; 282 Younger patients: 0% (preoperatively) versus 0.9% (postoperatively), n=105] (data not 283 shown). Figure 3B shows that elderly patients had higher level of calcium prior to and 5 284 years after BDP-DS compared to younger patients (Group effect, p=0.03). In both groups, 285 mean level of calcium was significantly decreased 5 years after BPD-DS compared to 286 mean level obtained pre-BPD-DS (Time effect, p=0.0001). Parathyroid hormone level 287 was significantly increased in each group 5 years after BPD-DS (Time effect, p=0.0001) 288 (data not shown). Severe calcium deficiency ($\langle 2g/L \rangle$) at last follow-up was low in both 289 groups (2.9% in elderly versus 1.9% in younger patients). Hemoglobin level was lower 5 290 years after surgery than before in both groups (Time effect, p=0.0001) (Figure 3C). 291 However, in both groups, no significant decrease in iron levels was observed after 5 years

of follow-up (**Figure 3D**) and an increase in folic acid and vitamin B12 levels was observed postoperatively (data not shown). The percentage of patients with hemoglobin value lower than 100g/L was very low and similar in both groups prior to and at the last follow-up (0% preoperatively versus 0.9% postoperatively in both groups (data not shown). There was no significant difference between the two groups for levels of hemoglobin and iron before and 5 years after BPD-DS (**Figure 3C and D**).

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Table 5 shows causes of late hospitalization related to bariatric surgery during follow-up.
 300 Including all patients, the main cause for rehospitalisation was malnutrition (8.1%). The 301 percentage of rehospitalisation for malnutrition tended to be higher in elderly patients 302 compared to younger ones (p=0.08). However, in both groups, the majority of patients 303 required only medical treatment. Surgery for malnutrition was required in 3 elderly 304 patients and in 1 patient of the younger group (p=0.27). Lengthening of the common 305 channel (typically from 100 to 200 cm along the biliary limb) was successful in all 306 patients. The percentage of late hospitalization for delayed fistula, stenosis, incisional 307 hernia, gastrointestinal bleeding, intestinal obstruction, diarrhea, abdominal pain, pulmonary embolism, pancreatitis and abscess was similar between the two groups 308 309 (**Table 5**). Surgery for intestinal obstruction was significantly higher in younger patients 310 compared to older ones (7.6% versus 0.9%, p=0.02).

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After a mean follow-up of 7.1 years (range: 6 months to 19 years), 9 (8.6%) long-term deaths in the elderly group were reported compared to 2 (1.9%) in younger patients (p=0.03) (data not shown). In the elderly group, 2 died from cancer, 1 from trauma, 1

315	from pulmonary disease, 2 from cardiac causes and 1 from ulcerative colitis. In this
316	group, two deaths were related to bariatric surgery (1 from intra-abdominal abscess and 1
317	from gastric fistula). In the younger group, 1 patient died from lung cancer and 1 patient
318	died from pulmonary problem (severe asthma). No significant difference was found
319	between the two groups for long-term deaths related to BPD-DS (p=0.20).

321 **DISCUSSION**

To our knowledge, this is the first study to clearly compare perioperative complications 322 323 and long-term results of open BPD-DS in elderly patients versus a matched control group 324 of younger patients. We tested the hypothesis that open BPD-DS is associated with 325 similar long-term benefits in elderly and younger patients, in terms of excess weight loss 326 and resolution of obesity-related comorbidities. We found that mean operative time, 327 hospital stay and blood loss were all slightly but significantly higher in the elderly group. 328 However, 30-day mortality rate was similar in both groups (0.9%, in each group) and in 329 acceptable ranges for open surgery performed an average 7 years ago. We found a trend 330 for an increased rate of major 30-days complications in the elderly group. Regarding 331 long-term results, we demonstrated that in both groups, weight loss remained relatively 332 stable over the years. After a mean follow-up of 7.1 years, there was no significant 333 difference between the two groups for %EWL, BMI and % of success IEW. Furthermore, most of the patients in both groups had a marked improvement or resolution of their 334 335 obesity-related comorbidities.

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One important finding in the present study is that our results showed significant and durable long-term weight-loss after BPD-DS in both younger and older patients, with a mean %EWL of 73% and 68% respectively. Consistent with our results, Buchwald et al. [10] reported in a meta-analysis that BPD-DS resulted in the greatest long-term %EWL (70.1%) compared to others surgeries. In both groups, we found that most of the patients had a successful long-term weight loss (>50%IEW). Furthermore, no revision surgery was performed for insufficient weight loss. Previous studies also reported clinically 344 significant excess weight loss and improvement in quality of life after bariatric surgery in 345 elderly patients, but most of these effects were not as significant as those observed in 346 younger patients [16, 26, 28, 37, 39]. However, most of these studies have only examined 347 short-term weight-loss (< 1 year of follow-up after surgery). In the present study, we also 348 reported that %EWL was significantly lower in elderly patients after 1 year of follow-up. 349 Nevertheless, these differences were not statistically significant after a mean follow-up of 350 7.1 years, suggesting that open BPD-DS results in substantial long-term weight-loss in 351 both younger and older patients.

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353 Our study also demonstrated that most of the patients in both groups had a marked 354 improvement or resolution of their obesity-related comorbidities. Even if the complete 355 resolution of hypertension was higher in younger patients compared to older ones, we 356 found that improvement of hypertension was clinically significant in both groups. The 357 resolution of type 2 diabetes and sleep appear was similar in both groups. Consistent with 358 our results, a meta-analysis by Buchwald et al. [9] reported that T2DM was improved or 359 resolved in 86.6% after bariatric surgery. According to a more recent meta-analysis, 360 T2DM resolution after BPD-DS was 89%, which is also comparable to our results [40]. 361 Leivonen et al. [23] demonstrated that the resolution of T2DM and hypertension was 362 similar between older and younger patients after 12 months post SG. Interestingly, Lynch 363 and Belgaumkar [17] also reported in a meta-analysis of 18 studies that the resolution of 364 hypertension, diabetes, sleep apnea and lipid abnormalities was similar to those observed 365 in younger patients.

367 Even if BPD-DS seems to be associated with higher perioperative risks and mortality rate 368 compared to others surgeries [41, 42], the 30-day mortality rate in our study was low and 369 similar to that of other bariatric surgery procedures performed by open surgery and in 370 similar periods (0-4.3%) [43]. Interestingly, we found no significant difference in early 371 mortality rate between the two groups (0.9%, in each group). In contrast to our results, 372 Flum et al. [25] previously reported that the early mortality rate after RYGB was 373 significantly higher in elderly (>65 years) compared to younger patients. In a cohort 374 obtained from the American College of Surgeons National Surgical Quality Improvement 375 Program database, Dorman et al. [24] demonstrated that older age tended to predict 376 mortality, but this was not statistically significant. Consistent with our results, Dunkle-377 Blatter et al. [26] reported no significant difference between older and younger patients 378 for 30-day and 90-day operative mortality rates. Considering that mortality rate may be 379 influenced by several factors such as the type of procedure, the volume of bariatric 380 surgery, the improvement of surgical management, the optimization of perioperative care 381 and the anesthesia [17, 43, 44], the comparison of mortality rate between studies remains 382 challenging. However, in our matched-control study, we reported no significant 383 difference in short-term or long-term mortality rate related to BPD-DS between younger 384 and older patients.

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Furthermore, our study demonstrated that elderly patients tented to have higher 30-day major complication rates. Even if our two groups were individually matched for gender, BMI, the presence of T2DM and year of surgery, it is important to take into consideration that elderly patients had a significantly higher number of pre-operative comorbidities and used a higher number of daily medications. As reported by others [16, 26, 28, 29, 43, 45], elderly patients are often a "higher-risk" group of patients with higher perioperative comorbidities. This could explain why we observed a trend for higher 30-day major complications and a significantly longer hospital stay. Dorman et al. [24] previously reported that elderly age (\geq 65 years) was an important risk factor for short-term prolonged hospital stay but it was not a significant predictor for major adverse events.

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397 As previously reported [6, 8, 46], the risk of BPD-DS in terms of late malnutrition and 398 nutritional deficiencies is real but with appropriate long-term follow-up of patients as 399 well as standardized vitamin and mineral supplementation, the risk is relatively low. The 400 present study demonstrated that after a mean 7.2 years of follow-up, the percentage of 401 severe hypoalbuminemia was low and similar in both groups. Mean level of albumin and 402 hemoglobin were slightly decreased after 5 years of follow-up in both groups. However, 403 we found that elderly patients tended to have higher rehospitalisation rates for 404 malnutrition. Our results suggest that long-term postoperative care remains essential in 405 both groups, especially in older ones. Rigorous nutritional monitoring may improve 406 management of potential deficiencies in all patients.

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Limits of the study should be acknowledged. Considering that laparoscopic BPD-DS has been introduced in 2006 in our institution and that one of the primary endpoints of the study was to examine long-term outcomes of BPD-DS, patients who underwent laparoscopic BPD-DS with standard intestinal limb lengths were excluded from the study. Several studies recently demonstrated the enhanced safety of laparoscopic bariatric 413 surgeries compared to open surgeries. Indeed, laparoscopic approaches seem to be related 414 to better outcomes in terms of mortality rate, length of stay and complications [43]. Most 415 importantly, we previously reported lower 30-day mortality rates, blood loss and shorter 416 hospital stays with laparoscopic BPD-DS [11], suggesting that the laparoscopic approach 417 may be beneficial in both younger and older patients. Another acknowledged limitation 418 of the study is that even if the data were collected prospectively, this study is still 419 retrospective. Furthermore, some data were missing and some of the information 420 regarding surgery and weight loss satisfaction were from a self-administered 421 questionnaire. Nevertheless, one of the major strength of our study is that we reported 422 long-term results of BPD-DS, using a matched-control group. Such studies are very 423 scarce in the literature. We also examined a rather large sample of patients for which we 424 also had detailed data on weight loss, comorbidities resolution, complications, short and 425 long-term mortality rates and nutritional parameters.

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In conclusion, our study suggests that open BPD-DS is associated with similar favorable long-term benefits in elderly and younger patients, in terms of weight loss and resolution or improvement of obesity-related comorbidities. As expected, rates of perioperative complications tend to be higher in the elderly population but this was not associated with increased mortality.

432

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439 CONFLICT OF INTEREST STATEMENT

- 440 A. Tchernof and L. Biertho are co-directors of a Research chair in bariatric and metabolic
- 441 surgery. A. Michaud, G. B. Marchand, M. Nadeau, S. Lebel, FS. Hould, S. Marceau, O.
- 442 Lescelleur, S. Biron, A. Tchernof and L. Biertho have no financial relationships relevant
- to this manuscript to disclose.
- 444

445 ETHICAL APPROVAL

- 446 For this type of study formal consent is not required. This study received approval from
- 447 the Ethics Committee of our institution.

448

449 **INFORMED CONSENT**

450 Does not apply.

451

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601 FIGURE HEADINGS

Figure 1: (A) Percentage of excess weight loss (%EWL) for the two groups after 6, 12,
24, 36, 48 and 60 months of follow-up; (B) %EWL, (C) percentage of total body weight
loss and (D) BMI for the two groups after a mean follow-up of 7.1±4.1 years. Mean ±
SEM are shown. * p≤0.05

606

Figure 2: Resolution of type 2 diabetes, hypertension and obstructive sleep apnea in each group after a mean follow-up of 7.1 ± 4.1 years. (**A**) Percentage of patients with type 2 diabetes resolved, improved, unchanged or unknown; (**B**) Percentage of patients with hypertension resolved, improved, unchanged or unknown; (**C**) Percentage of patients with obstructive sleep apnea resolved, improved, unchanged or unknown. * Statistically significant difference between younger and elderly patients using chi-square test (p=0.008)

614

615 **Figure 3:** Mean levels of (A) albumin (g/L) (Elderly patients: n=51; Younger patients: 616 n=46), (**B**) calcium (g/L) (Elderly patients: n=54; Younger patients: n=43), (**C**) 617 hemoglobin (g/L) (Elderly patients: n=63; Younger patients: n=53) and (D) iron 618 (mmol/L) (Elderly patients: n=72; Younger patients: n=56) prior to and 5 years after 619 BPD-DS in elderly and younger patients. Mean \pm SEM are shown. Repeated-measures analysis of variance was used to examine the effect of group [younger patients (age ≤ 55 620 years) versus elderly patients (age ≥ 60 years)], time (pre-BPD-DS and 5 years post-621 BPD-DS) and time-by-group interaction. 622

624 **TABLES**

Variables	$All \qquad Age \le 55 \ yea$		Age≥60 years	P value	
Patients (n)	210	105	105	-	
Gender (M : F)	82:128	41:64	41:64	NS	
Age (years)	51.4±12.1	40.4 ± 7.0	62.3±2.0	≤0.0001	
BMI (kg/m^2)	$50.9{\pm}6.8^{a}$	50.9 ± 6.8	50.9 ± 6.8	NS	
Weight (kg)	138±26	142±27	133±24	≤0.05	
Preoperative comorbidities					
Diabetes	57% (120)	57% (60)	57% (60)	NS	
Cardiovascular disease	20% (42)	8% (8)	32% (34)	≤0.0001	
Hypertension	72% (151)	63% (66)	81% (85)	0.004	
Dyslipidemia	38% (79)	33% (35)	42% (44)	0.20	
Obstructive sleep apnea	64% (134)	56% (59)	71% (75)	0.02	
Mean number of comorbidities	4.3±2.0	3.8±1.9	4.7±2.1	0.002	

625 **Table 1: Preoperative characteristics of the study population**

626 Data are presented as mean \pm SD or percentage (n). Wilcoxon test was used for analysis

of age, BMI, weight and number of comorbidities; Chi-square test was used for analysis

of gender and preoperative comorbidities. The two groups were matched for age, gender,

629 BMI, diabetes and the year of operation. M= male, F= female, BMI= body mass index 630 a range=40.1-75.9kg/m²

Tuble 2. I erroperative data				
Variables	All	Age ≤ 55 years	Age ≥ 60 years	P value
Operative time (min)	170.5 ± 44.1	162.5±39.9	178.6±46.7	0.01
Blood loss (ml)	542±399	474±241	593±484	0.05
Postoperative hospital stay (d)	8.2 ± 6.1	6.4 ± 2.2	10.2 ± 8.3	0.0001
30-day mortality rate	0.9% (2)	0.9% (1)	0.9% (1)	NS
10-day reoperation rate	4.3% (1)	3.8% (4)	4.8% (5)	NS

632 **Table 2: Perioperative data**

633 Data are presented as mean \pm SD or percentage (n). Student's *t* test was used for analysis

634 of operative time, blood loss and postoperative hospital stay; Chi-square test was used for

635 analysis of mortality rate and reoperation rate. d=days

Variables	All (n=210)	Age ≤ 55 years (n=105)	Age ≥ 60 years (n=105)	P value
Major				
Gastric leak	0.9% (2)	0.9% (1) ^a	0.9% (1)	NS
Duodenal leak	2.4% (5)	1.9% (2)	2.9% (3)	NS
Ileoileal anastomosis leak	0.5% (1)	0	0.9% (1)	NS
Intra-abdominal abscess	1.9% (4)	0.9% (1)	2.9% (3)	NS
Pancreatitis	0.9% (2)	0	1.9% (2)	NS
Biliary leak	0.5% (1)	0.9% (1)	0	NS
Pneumonia	0.9% (2)	0.9% (1)	0.9% (1)	NS
Abdominal hemorrhage	0.9% (2)	1.9% (2)	0	0.16
Pulmonary embolism	0.5% (1)	0	0.9% (1)	NS
Small bowel obstruction	1.4% (3)	0.9% (1)	1.9% (2)	NS
Stenosis	0.5% (1)	0	0.9% (1)	NS
Others	0.9% (2)	0	1.9% (2) ^a	0.16
Total	12.4% (26)	8.6% (9)	16.2% (17)	0.09

637 **Table 3: Major complications in first 30 postoperative days**

638 Data are presented as percentage (n). Chi-square test was used for analysis of variables.^a

639 including one death

Variables	All (n=210)	Age ≤ 55 years (n=105)	Age ≥ 60 years (n=105)	P value
Minor				
Wound infection	1.9% (4)	0.9% (1)	2.9% (3)	NS
Food intolerance	4.8% (10)	4.8% (5)	4.8% (5)	NS
Urinary complications	0.9% (2)	0	1.9%(2)	NS
Atelectasia	0.9% (2)	0	1.9% (2)	NS
Respiratory insufficiency	0.9% (2)	0	1.9% (2)	NS
Digestive hemorrhage	0.9% (2)	0.9% (2)	0	NS
Renal colic	0.5% (1)	0.9% (1)	0	NS
Dyspepsia	0.5% (1)	0.9% (1)	0	NS
Total	11.4% (24)	9.5% (10)	13.3% (14)	NS

641 **Table 4: Minor complications in the first 30 postoperative days**

642 Data are presented as percentage (n). Chi-square test was used for analysis of variables.

	All $Age \leq 55$ years		Age \geq 60 years		
Variables	% (n)	% (n)	Required	% (n)	Required
Malnutrition	8.1% (17)	4.8% (5)	0.9% (1)	$\frac{11.4\% (12)^{a}}{11.4\% (12)^{a}}$	1.4% (3)
Food intolerance	1.4% (3)	1.9% (2)	0.570 (1)	0.9% (1)	0.9%(1)
Delayed fistula	2.9% (6)	1.9% (2)	1.9% (2)	3.8% (4)	2.9% (3)
Stenosis	1.4% (3)	1.9% (2)	1.9% (2)	0.9% (1)	0
Incisional hernia	3.8% (8)	4.8% (5)	4.8% (5)	2.9% (3)	2.9% (3)
Gastrointestinal bleeding	0.5% (1)	0	0	0.9% (1)	0
Intestinal obstruction	5.2% (11)	7.6% (8)	7.6% $(8)^{b}$	2.9% (3)	0.9% (1)
Diarrhea	0.9% (2)	1.9% (2)	0	0	0
Abdominal pain	3.3% (7)	3.8% (4)	0	2.9% (3)	0
Pulmonary embolism	0.5% (1)	0	0	0.9% (1)	0
Pancreatitis	0.5% (1)	0.9% (1)	0	0	0
Abscess	2.4% (5)	2.9% (3)	2.9% (3)	1.9 (2)	1.9% (2)

644 Table 5: Causes of late hospitalization related to bariatric surgery during follow-up

645 Data are presented as percentage (n). Chi-square test was used for analysis of

646 variables. ^ap≤0.10, comparing percentage of hospitalizations between elderly and younger

647 patients; ^bp \leq 0.05, comparing percentage of patients who required surgery between elderly

648 and younger patients.







В



С

Obstructive sleep apnea



