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Metabolic Surgery in Type 2 Diabetes: Roux-en-Y Gastric Bypass or Sleeve Gastrectomy as Procedure of Choice?

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Abstract In recent years, a marked increase in the relative use of sleeve gastrectomy (SG) has occurred. However, long-term head-to-head comparison of the impact of this bariatric surgery (BS) procedure with the still considered "gold standard" Roux-en-Y gastric bypass (GBP) in subjects with type 2 diabetes mellitus (T2DM) is surprisingly low. The aim of this review manuscript is to appraise current evidence on the potential of GBP and SG as long-term therapeutic tool for subjects with T2DM. In our opinion, unfortunately, review of current literature does not allow to properly answer which of the two surgeries would be better as procedure of choice for subjects with T2DM. Arguably, the apparent superiority of GBP over SG could be overcome by the addition of a malabsortive component to SG in a staged approach restricted to those failing to achieve the desired metabolic outcomes. Nonetheless, whether this serves as basis for the election of SG as primary strategy for those with T2DM is questionable.

Keywords Sleeve gastrectomy · Gastric bypass · Duodenal switch · Type 2 diabetes mellitus · Weight loss

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Introduction

Several studies have shown that regardless of the bariatric surgery (BS) technique, established surgical procedures are associated with larger and more sustained weight loss and better obesity-related comorbidity outcomes as compared to non-surgical interventions [1–3, 4••, 5]. However, the cornerstone meta-analysis by Buchwald et al. clearly showed that the extent of the impact and time relationship of improvement of comorbidities varies following different surgical techniques [3]. A gradient of increasing effectiveness as well of increasing potential surgery-derived complications was described following gastric banding (GB), vertical-banded gastroplasty (VBG), Roux-en-Y gastric bypass (GBP), and biliopancreatic diversion/duodenal switch (BPD/DS). In this scenario, a more favorable benefit to risk ratio led some authors to propose GBP as the "gold standard" BS procedure [6].

At the beginning of this century, sleeve gastrectomy (SG) emerged as a new BS approach. It was initially conceived as the first operation of a 2-staged approach to duodenal switch (DS) or GBP for the super obese patient [7, 8]. Nonetheless, the introduction of SG was accompanied by reports on promising short-term weight loss outcomes and also on the amelioration of obesity-related comorbidities at comparable rates to GBP [9–11]. These results, along with the easier surgical technique of SG compared to GBP, led to an increasing popularity of SG as a stand-alone procedure not only for those with super obesity but also for subjects with lower degrees of obesity. In fact, a recent survey on the use of different BS techniques worldwide has shown that although GBP is still the most commonly performed procedure (45 % of a total of 468,609 BS procedures performed in 2013), SG is already second and close (37 %) to the currently considered as gold standard [12•]. Of note, in 2013, SG ranked first in the USA/Canada and Asia/Pacific regions. Furthermore, the survey unveiled the marked shift in the relative percentages of the two BS procedures that has occurred in recent years. According to a previous report, in 2008, GBP already represented 49 % of the BS procedures performed worldwide whereas SG represented only 5.3 %.

Against this background, the aim of this manuscript is to review current evidence and to provide critical analysis on the relative clinical impact of the two most commonly performed BS techniques, namely GBP and SG, especially on type 2 diabetes (T2DM) and weight loss (WL). Ample short-term evidence about the benefits and risks of bariatric surgery up to 1 year after surgery is available. Nonetheless, as BS is intended as a long-term solution, we will emphasize the relative long-term impact of GBP and SG on health outcomes.

GBP and SG and Diabetes Outcomes

The current guidelines of the American Diabetes Association (ADA) endorse BS in T2DM subjects with a BMI≥35 kg/m^2 especially if diabetes or associated comorbidities are difficult to control with lifestyle and pharmacological therapy [13]. Additionally, since 2011, the International Diabetes Federation (IDF) supports BS in subjects with T2DM and a BMI 30–35 kg/m^2 provided hemoglobin A1c (HbA1c) values are >7.5 % despite optimized conventional therapy, especially if weight is increasing, or if other weight responsive comorbidities are not reaching the target on conventional therapy [14]. Although treatment goals and plans for patients with T2DM should be tailored and take patient preferences into account, foundations for the prevention of microvascular and macrovascular chronic complications of T2DM include achieving an HbA1c <7 %, LDL cholesterol <100 mg/dl, and systolic and diastolic blood pressure <140 and <90 mmHg [13], respectively. In this scenario, analysis of diabetes outcomes associated with BS should take into account patient characteristics—with special emphasis on those beyond the very early stages of the disease, and long-term rather than short-term results—as BS is not intended as just a quick fix for prevailing hyperglycemia.

Three different meta-analyses comparing the impact of SG versus GBP on T2DM have been reported in 2015. Wang et al. restricted their meta-analysis to published randomized clinical trials (RCT) comparing the impact of the two types of surgeries in subjects with T2DM aged >18 years and with a BMI >25 kg/m^2 [15•]. The authors identified 4 RCT, adding up a total of 127 and 129 GBP- and SG-operated subjects. However, mini-GBP rather than Roux-en-Y GBP was used in one of the studies [16]. The range of diabetes duration was wide, but neither baseline HbA1c nor the proportion of subjects with insufficient metabolic control, despite optimized conventional medical therapy (i.e., percentage of subjects on insulin prior to surgery), was provided. No significant difference was identified in the change in HbA1c between the two surgical techniques (mean difference, 0.41 %; 95 % CI, –0.09 to 0.91). However, the authors reported that GBP was associated with a significantly larger benefit on cardiovascular (CV) risk because of its larger effect on HDL and LDL cholesterol. Unfortunately, post-surgical follow-up in the selected studies was short (6 months in one study and 12 months in three studies), precluding conclusions on the long-term efficacy of surgery. A second meta-analysis has been conducted by Cho et al. [17] who reported on the diabetes remission rates encountered in three retrospective clinical studies, six prospective clinical studies, and two RCTs comparing GBP and SG published between 2008 and 2013. Interestingly, only two out of the four RCTs included in Wang's et al. meta-analysis were chosen by Cho et al. By selection criteria, the studies included a minimum post-surgical follow-up of 12 months, with 7 out of the 11 studies providing up to 12 month data, but only 2 up to 24 months, and only 2 up to 36 months. Overall, 429 SG- and 428 GBP patients were included. The pooled pre-surgical HbA1c was 7.5 % in both study arms, but the duration of T2DM and percentage of subjects on insulin therapy was not provided. In this meta-analysis, the remission rates of T2DM were not significantly different (p=0.07) following the two surgical techniques [SG 63 % (range 27–86 %); GBP 74 % (range 42–96 %)]. Finally, Panunzi et al. conducted a systematic review and meta-analysis of published observational and interventional trials with the primary aim of identifying predictors of T2DM remission following BS in subjects with a BMI >35 kg/m^2 or <35 kg/m^2 [18]. Although not restricted to GBP and SG, as a secondary objective, the authors analyzed rates of remission following different types of BS. A total of 94 studies were evaluated, including 6 studies comparing GBP and SG, and 31 and 13 studies with GBP and SG as the sole surgical arm. Prior to surgery, HbA1c in subjects with a BMI >35 kg/m^2 was 7.5 %, being 8.9 % in those with BMI <35 kg/m^2. Although the meta-analysis was limited by the use of different definitions of diabetes remission in different studies, in this meta-analysis, the remission rate following GBP (77 %; 95 % CI 72–82 %) was larger as compared to SG (60 %; 95 % CI 51–70 %). Unfortunately, several additional limitations hamper the meta-analysis by Panunzi et al. As in the other meta-analysis, the duration of diabetes and treatment modality were not provided. Furthermore, length of follow-up was not more than 1 year in the majority of studies evaluated. Thus, overall it could be concluded that the above mentioned meta-analysis shed little light on the relative impact of GBP or SG specifically in subjects with a BMI >35 kg/m^2 for whom BS may be considered according to the ADA criterion, as well as for those with a BMI 30–35 kg/m^2 considered as BS candidates by the IDF [1, 2].

The best evidence available on the mid-term relative effects of GBP and SG on T2DM comes from the 3-year report of the STAMPEDE trial [4••]. Importantly, the study was not specifically designed to compare the two surgical techniques but rather to compare intensive medical therapy with surgical treatment as a means of improving glycemic control in obese subjects with T2DM. Thus, the sample size was calculated to compare medical to surgical arms rather than to achieve sufficient statistical power to compare GBP and SG. However, as a RCT, it adheres to the currently considered best study design to address the scientific question of our review manuscript. Participants allocated to the surgical arms in the STAMPEDE trial presented a pre-surgical HbA1c of 9.4 %, mean diabetes duration of 8.2 years, and 43 % were on insulin prior to surgery. At 3 years, the primary study endpoint (HbA1c ≤6 % with or without medical therapy) was achieved in a comparable proportion of subjects in the GBP and SG arms (respectively, 38 and 24 %; $p=0.17$). The less stringent but clinically meaningful HbA1c <7 % cut-off was achieved in 65 % of the study participants in both surgical groups ($p=0.94$). Nonetheless, a larger impact of GBP on glycemic control was suggested by the larger—albeit not statistically significant ($p=0.09$)—proportion of GBP patients fulfilling the primary end point both at 1 and 3 years of follow-up (GBP 76 % versus SG 50 %), and the proportion of subjects with HbA1c <7 % without diabetes medications at 3-years (GBP 58 % versus SG 33 %; $p=0.01$). In the STAMPEDE trial, neither baseline HbA1c nor insulin therapy prior to surgery independently predicted achievement of the primary study endpoint in the surgical groups. A diabetes duration of less than 8 years was significantly associated with attainment of HbA1c <6 % in the surgical groups [OR 3.3 (95 % CI 1.2 to 9.1); $p=0.02$], but comparison on the relative effect of GBP and SG in subjects above or below this threshold was not reported. Changes from baseline in other CV risk factors (LDL- and HDL-cholesterol, triglycerides, systolic, and diastolic blood pressure) were comparable following GBP and SG.

An additional illustration of potential limitations of the durability of the glycemic effects of SG in comparison with GBP comes from observational studies from ours as well as other groups [19, 20•, 21]. Retrospective analysis of the prospectively collected database from our cohort of subjects with T2DM undergoing GBP or SG as the first BS procedure showed SG was an independent predictor of relapsing diabetes at 48.7 months of follow-up [GBP: Reference; SG 2.239 (95 % CI 1.067–5.124); $p=0.034$], whereas it was not at shorter (35.4 months) follow-up [19, 20•]. Moreover, in a logistic regression analysis of factors associated with lack of achievement of HbA1c <7 % in the subgroup of T2DM subjects on insulin therapy prior to surgery in our cohort ($n=63$), SG emerged as an independent predictor of an insufficiently controlled metabolic outcome [GBP: Reference; SG 6.594 (95 % CI 2.671–16.288); $p<0.001$], along with diabetes duration and length of follow-up (Vidal et al., unpublished observation). Likewise, Brethauer et al. reported a higher recurrence rate and lesser durability of the improvement in HbA1c following SG as compared to GBP in their series of T2DM subjects [21]. Admittedly, lack of randomization is a limitation of these observations. Furthermore, achievement of diabetes remission or HbA1c <7 % in subjects with advanced diabetes following GBP was not universal [19, 20•, 21, 22•]. Nonetheless, although confirmation of these findings would only arise from studies with a similar length of follow-up but of better quality, we deem that they raise questions about the durability of the effects on glycemic control of SG as a stand-alone procedure.

GBP and SG and Weight Loss

The results of studies on the outcomes of T2DM following GBP and SG have fueled a paradigm shift in the field [23]. This area has drifted from the term BS, which focuses primarily on WL and secondarily on the resolution of obesity-related comorbidities. Alternatively, acknowledgment of the impact of the modifications of the gastrointestinal tract on metabolic diseases—particularly T2DM—has led to the emergence of the term metabolic surgery. As a matter of fact, several lines of evidence suggest participation of WL-independent mechanisms on the effects of GBP and SG on glucose metabolism [24–26]. As mentioned in the previous section, indirect evidence for such WL-independent effects comes from the observation of the requirement of lesser amounts of hypoglycemic agents to achieve HbA1c goals following GBP as compared to SG [4••]. Moreover, Kashyap et al. reported on a larger improvement in insulin sensitivity and pancreatic beta cell function despite comparable WL in GBP- relative to SG-patients at 2-year follow-up of the STAMPEDE trial [24]. However, currently available data strongly supports the amount of WL and maintenance of WL also plays a role in the post-surgical amelioration of T2DM following these surgical techniques. For instance, in the 3-year report of the STAMPEDE trial discussed above, a change in the BMI was the only independent predictor [OR for each 1-unit decrease in BMI 1.41 (95 % CI 1.22–1.64); $p<0.001$] of the achievement of the primary outcome measure of the study, that is HbA1c <6 % with or without medical therapy [4••]. As mentioned above, analysis of the STAMPEDE study participants restricted to those in the surgical arms also identified a duration of

T2DM longer than 8 years as an independent predictor, but this barely modified the relationship between the change in BMI and meeting the criterion for the primary study endpoint [OR 1.33 (95 % CI 1.15–1.56); $p<0.001$]. Similarly, in the Diabetes Surgery Study by Ikramuddin et al. in which medical therapy and GBP surgery were compared, a WL >10 % relative to baseline [OR 2.3 (95 % CI 1.2–4.5)] rather than GBP [OR 0.96 (95 % CI 0.22–4.24)] independently predicted attainment of the triple metabolic endpoint (HbA1c <6.5 %, plus LDL cholesterol <100 mg/dl, plus systolic blood pressure <130 mmHg) defined as the primary study outcome at 12 months after surgery in the entire cohort [27]. Of note, the impact of a WL greater than 10 % did not differ ($p=0.8$) when the analysis was performed separately within each of the two treatment arm groups [medical therapy: OR 2.6 (95 % CI 1.1–5.9); GBP group: OR 2.2 (95% CI 1.1–4.7)]. On the other hand, although not consistently, weight regain has been associated with relapsing T2DM in several studies [19, 21, 28, 29]. Obviously, it could be argued that WL along with reduced fat mass is a surrogate marker rather than a factual mechanism underlying the metabolic benefits of GBP and SG. Nonetheless, beyond mechanistic considerations, the data discussed above strongly suggest that the WL response following GBP or SG merits consideration in this review article as an important outcome of these surgical techniques.

Unfortunately, comparisons of the long-term WL outcomes between GBP and SG are also scarce. Puzziferri et al. recently reported a systematic review of the English literature on BS studies available published up to May 2014 that fulfilled the criteria of reporting on at least 20 participants with a BMI ≥35 kg/m^2, had more than 2 years of outcome information, and included follow-up measures for at least 80 % of the participants [30]. The authors could identify only 29 studies meeting pre-defined inclusion criteria, including 11 GBP (6 prospective, 5 retrospective cohorts) and 2 SG (retrospective) studies. The mean follow-up ranged from 2 to 5 years in GBP studies and were from 2 to 4 years respectively in the two selected SG case series. Sample-size weighted mean excess weight loss (EWL) was 65.7 % after GBP and was comparable to that in SG studies (64.5 %). Nonetheless, direct comparison of the two surgical procedures was not attempted in any of the studies reviewed.

To our knowledge, head-to-head comparison of WL after GBP or SG with follow-up beyond 1 year has been reported in three separate RCTs [4••, 31, 32]. The recently reported 3-year data of the RCT STAMPEDE trial, including only patients with T2DM, showed a larger reduction in body weight following GBP [mean±standard deviation (SD): −26.2±10.6 kg] as compared to SG [−21.3±9.7 kg; $p=0.02$] [4••]. Of note, larger WL and BMI drop were also reported in association with GBP as compared to SG in a previous publication of the 1-year results of the same study [33]. In contrast, the study by Kehaigas et al. showed larger percent EWL (%EWL) after SG at 1 year (SG 72.9 % versus GBP 65.6 %; $p=0.13$), but comparable %EWL at 3-years of follow-up (SG 68 % versus GBP 62 %; $p=0.13$) [31]. Furthermore, in this study, the proportion of patients who achieved successful WL (EWL> 50 %) at 3 years after surgery was 77 % after GBP and 83 % after SG ($p=0.74$). Finally, in the study by Peterli et al., data on the whole data set (GBP: $n=107$, SG: $n=110$) showed comparable %EWL following the two surgical procedures at 1 year of follow-up, but a trend towards lesser %EWL associated with SG in the subset of participants who had already completed 3-years of follow-up at the time of the first publication of the results of this RCT (GBP: $n=32$, %EWL= 72.8; SG: $n=110$, %EWL 63.3) [33]. The impact of differences in surgical techniques or clinical characteristics of participants on WL outcomes among the three studies is an open question. The study by Kehaigas et al. and Peterli et al. involved mainly nondiabetic subjects (respectively, 17 and 25 %), the characteristics of those with T2DM were not specified, and the mean BMI among participants in the three studies differed.

To date, data on WL and WL maintenance beyond 5 years of follow-up after GBP or SG is available only from non-RCT studies or case series reports. Six-year follow-up data from the *Swedish Obese Subjects* study showed maximum WL after GBP was reached at approximately 24 months after surgery (WL relative to baseline: −34.5±8.4 %), and was ensued by variable weight regain (9.8±8.2 kg) [34]. Similar results were reported by Adams et al. in a case series of GBP subjects from Utah (USA), with 94 % (95 % CI 92–96 %) and 76 % (95 % CI 72–81 %) of study participants presenting a WL ≥20 % respectively at 2 and 6 years after surgery [6]. Edholm et al. reported an excess BMI loss of 63.3 % at 11.4 years mean follow-up after GBP, with a similar WL observed across post-surgical observation (7–17 years) [35]. Interestingly, comparable %EWL (67.6 %) in a series of 228 subjects that had been followed for an equivalent length of follow-up (11.4 years) after GBP was found by Christou et al. [36]. However, as in the series discussed above, at 11.4 years, %EWL was significantly lower as compared to nadir weight (88.6 %; $p<0.001$) and was deemed insufficient (%EWL<50 %) in 35 % of the study participants. Similarly, systematic reviews of SG series with longer follow-up (5 or more years) have shown a variable mean EWL (range 43–86 %), and declining mean %EWL over time (respectively, 62.3, 53.8, 43, and 54.8 % at 5, 6, 7, ≥8 years) [37]. Nonetheless, comparison of GBP and SG outcomes was not attempted in any of the above mentioned studies.

We recently reported on the WL outcomes of a series of 658 subjects that underwent GBP ($n=464$) or SG ($n=194$) as the first BS procedure, and for whom a mean follow-up of 55.7 months (range 30–68) was available [38••]. In the entire cohort, WL was maximal at 23.7±15.7 months after surgery and corresponded to a EWL of 81.7±19.2 %. At the last evaluation, EWL was 65.3±22.8 % (corresponding to a weight regain of 9.2±8.4 kg or 20.9±11.9 % relative to nadir weight). Analysis of covariance accounting for differences between surgical groups at baseline showed %EWL at nadir (GBP 81.3±0.8 versus SG 83.0±1.4 %) and the time to nadir weight after surgery (GBP 24.4±0.7 versus SG 22.2±1.2 months) were not significantly different between surgical cohorts (respectively $p=0.952$ and $p=0.136$). However, weight regain ensuing nadir weight was larger after SG as compared to GBP (respectively, 10.6±0.6 kg or 24.1±1.4 %, and 8.6±0.4 kg or 19.5±0.9 %; both $p<0.01$). Of note, Cox regression analysis showed SG was an independent predictor of poor WL maintenance after surgery (EWL<50 % at last follow-up visit) [GBP: Reference; SG: OR 1.775 (95 % CI 1.17–2.70); $p<0.01$]. Remarkably, SG was not independently associated with poor WL maintenance when the analysis was limited up to 4-years of follow-up data. Lesser EWL at >5 years after SG as compared to GBP in subjects with T2DM was also reported by Brethauer et al. (GBP 60.5±24.6 %, SG 49.5±24.9 %; $p=0.047$) [21].

In summary, current data suggest long-term superiority of GBP over SG on the metabolic control of T2DM could be accounted both by the larger WL and larger contribution of WL-independent mechanisms.

Sleeve Gastrectomy as a Starting Strategy?

It has been shown that BPD/DS is the BS technique associated with best WL and largest improvement of T2DM [3, 18]. The superiority of BPD/DS over GBP for the control of hyperglycemia in subjects with T2DM has been shown in several RCTs [5, 39, 40]. Thus, it could be argued that the above reviewed clinically meaningful long-term superiority of GBP over SG as stand-alone surgery for subjects with T2DM could be overcome with the addition of the malabsortive component of DS as the second-stage to subjects failing to obtain the expected results with SG as the primary procedure [41]. Importantly, it could be argued although picking GBP as the metabolic surgery of choice would provide better results relative to SG, the former is neither associated with universal remission of T2DM, nor with null risk of relapsing T2DM or deterioration of metabolic control long term after surgery [19, 20•, 21, 22•, 28].

Retrospective analysis of single-center case series of T2DM subjects who underwent SG as a stand-alone procedure or one-stage DS up to 2 years of follow-up showed superiority of the latter in terms of WL (EWL at 2 years: SG 51±19 % versus DS 86±15 %; $p<0.001$) and remission rates of T2DM (T2DM remission at 2 years: SG 56 % versus DS 90 %; $p<0.001$) [42•]. Among those on insulin therapy prior to surgery, SG and DS were associated with 22 and 81 % remission rates of T2DM, respectively. Importantly, Iannelli et al. have shown initial SG followed by DS yields %EWL and remission rates of comorbidities comparable to those following single-staged DS [43•]. Unfortunately, the study was limited to subjects with a BMI>50 kg/m^2 prior to SG. Nevertheless, data from this study would support SG as a starting strategy as it would be useful in a significant proportion of subjects, and thus, a smaller percentage would be exposed to the commonly encountered nutritional complications associated with DS [44, 45].

Although different surgical strategies have been defined to rescue unsuccessful outcomes of SG, surgical approaches to improve poor WL or insufficient amelioration of T2DM following GBP are less well defined [46–51]. Following "failed" SG, resleeve, conversion to GBP, DS, or single-anastomosis duodenoileal bypass have been proposed [46–48]. Data suggest amid those patients undergoing conversion, DS would provide the best results although at the expense of higher nutritional complications rates [48–50]. Sanchez-Pernaute et al. have recently reported on the effects of a single-anastomosis duodenoileal bypass—a one-loop duodenal switch with a 250-cm common limb—as the second step for patients with insufficient WL ensuing SG [49]. Interestingly, although in a short series of subjects, the mean EWL improved from 39.5 to 72 % at 2 years after the second-step surgery and complete remission was found in 88 % of those with T2DM at the end of follow-up. Unfortunately, direct comparison of this surgical approach with DS has yet to be reported.

Conclusions

In summary, although the percentage of SG as a stand-alone BS procedure has increased dramatically over the last years, head-to-head comparison of this surgical procedure with the still considered "gold standard" GBP is surprisingly low. In this scenario, the question as to which is the most suitable surgical strategy for subjects with T2DM remains open. Future studies should aim to further stratify subjects with T2DM. Information on the long-term impact of GBP and SG on those failing to achieve proper metabolic control while on conventional medical therapy is scarce and would be of utmost interest to specifically address the role of surgery in those considered to qualify according to the ADA (BMI>35 kg/m^2) or IDF (BMI 30–35 kg/m^2) criteria [13, 14]. Although offering a 2-staged approach to those that do not achieve proper WL and/or T2DM outcomes could be considered a sound option, it requires further validation. In this lines, the potential detrimental consequences of diabetes relapse T2DM following SG on the subsequent metabolic response to rescue therapy need to be taken into consideration. According to the last Worldwide Bariatric Surgery report, DS represents only 1.5 % of all the whole BS procedures [12•]. Although the reasons for the low priority given to DS by surgeons worldwide was not analyzed, careful evaluation of the nutritional consequences of a paradigm shift towards higher utilization of DS as a long-term tool for the treatment of T2DM would be advisable. Finally, although intensification of medical therapy could be considered as an acceptable alternative to handle those failing to achieve optimal glycemic goals after GBP or SG but not failing to successfully lose weight, this approach has not been properly tested. In short, much remains to be done to properly move the field ahead.

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Compliance with Ethics Guidelines

Conflict of Interest Josep Vidal, Amanda Jiménez, Ana de Hollanda, Lílliam Flores, and Antonio Lacy declare that they have no conflict of interest.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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•• Of major importance

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