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Cost-effectiveness and Budget Impact of Obesity Surgery in Patients with Type 2 Diabetes in Three European Countries(II)

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Abstract
Background This study aimed to establish a payer-perspective cost-effectiveness and budget impact model of adjustable gastric banding (AGB) and gastric bypass (GBP) vs. conventional treatment (CT) in patients with a body mass index (BMI)≥35 kg.m^{-2} and type 2 diabetes mellitus (T2DM) in Austria, Italy, and Spain.
Methods A health economics model described in a previous publication was applied to resource utilization and cost data in AGB, GBP, and CT from Austria, Italy, and Spain in 2009.
Results The base case time scope is 5 years; the annual discount rate for utilities and costs is 3.5%. In Austria and Italy, both AGB and GBP are cost-saving and are thus dominant in terms of incremental cost-effectiveness ratio compared to CT. In Spain, AGB and GBP yield a moderate cost increase but are cost-effective, assuming a willingness-to-pay threshold of 30,000 euro per quality adjusted life-year. Under worst-case analysis, AGB and GBP remain cost-saving or around breakeven in Austria and Italy and remain cost-effective in Spain.
Conclusion In patients with T2DM and BMI≥35 kg.m^{-2} at 5-year follow-up vs. CT, AGB and GBP are not only clinically effective and safe but represent satisfactory value for money from a payer perspective in Austria, Italy, and Spain.

Keywords Obesity surgery · Gastric bypass · Adjustable gastric banding · Cost-effectiveness · Budget impact · EQ-5D utility · Diabetes

Abbreviations

ABG	Adjustable gastric banding
BI	Budget impact
CT	Conventional treatment
DRG	Diagnostic-related group
EQ-5D	EuroQol three-level five-dimensional
GBP	Gastric bypass
HTA	Health technology assessment
LKF	Leistungsorientierte Krankenanstaltenfinanzierung: the point-based Austrian service-based hospital funding
ICER	Incremental cost-effectiveness ratio

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Table 1 Base case input—cost of AGB—share funded by statutory payers

Country	Austria		Italy		Spain	
Health care resources	units	€/unit	units	€/unit	units	€/unit
Preoperative assessment prior to initial admission						
Preoperative assessment (summary)	1.00	209.76	1.00	520.52	1.00	804.01
Initial hospital admission for surgery						
Hospital stay (all-inclusive lump)	1.00	3,633.00	1.00	5,496.00		
Hospital stay—per diem cost					3.50	319.64
Surgery—overhead (h)					1.91	395.65
AGB laparoscopic implant					1.00	1,300.00
Annual follow-up—years 1 through 5						
Average annual cost	1.00	164.62	1.00	365.87	1.00	409.79
Complications						
Average cost per patient	1.00	340.29	1.00	304.58	1.00	311.48
Total discounted—annual 3.5%	€ 4,784.88		€ 7,759.26		€ 5,995.08	

QALYs Quality adjusted life-years
T2DM Type 2 diabetes mellitus
WTP Willingness to pay: the maximum ICER accepted by health care payers

Introduction

Consensus conferences and guidelines establish that bariatric surgery can be proposed to adults with a body mass index (BMI)≥35 $kg.m^{-2}$ and type 2 diabetes mellitus (T2DM), when at least 1 year of well-conducted medical treatment has failed and in the absence of contraindications [1]. Evidence shows that both gastric bypass (GBP) and adjustable gastric banding (AGB) are safe and able to produce significant BMI reduction sustained at 5-year follow-up, as well as frequent remission of T2DM [2]. The cost of bariatric surgery remains a concern to payers across Europe, and resolving concerns require a quantification of budget impact (BI) and value for money. Bariatric surgeons in Austria, Italy, and Spain have examined the cost consequences and health value for money if a given number of patients are treated by GBP or AGB or kept on conventional treatment (CT).

Methods and Sources

The method adopted in this work is similar to the one used in the UK, Germany, and France 3 years earlier and is

Table 2 Base case input—cost of laparoscopic GBP—share funded by statutory payers

Country	Austria		Italy		Spain	
Health care resources	units	€/unit	units	€/unit	units	€/unit
Preoperative assessment prior to initial admission						
Preoperative assessment (summary)	1.00	209.76	1.00	538.10	1.00	859.95
Initial hospital admission for surgery						
Hospital stay (all-inclusive lump)	1.00	4,941	1.00	5,496.00		
Hospital stay—per diem cost	1.00[a]	289.50			4.88	296.96
Surgery—overhead (h)					3.84	529.68
Device set specific for laparoscopic GBP					1.00	2,000.00
Annual follow-up—years 1 through 5						
Average annual cost	1.00	161.88	1.00	393.80	1.00	425.82
Complications						
Average cost per patient	1.00	409.29	1.00	230.22	1.00	425.82
Total discounted—annual 3.5%	€ 6,360.89		€ 7,830.51		€ 8,344.42	

[a] Intensive care unit per diem supplementary LKF tariff to lump sum LKF tariff in Austria

Table 3 Base case input—cost of conventional treatment—share funded by statutory payers

Country	Austria		Italy		Spain	
Health care resources	Units	€/unit	Units	€/unit	Units	€/unit
Treatment during year 1						
Physician consultations	3	4.18	4	12.91	2	40.95
EKG					2	4,390
Nurse consultations			4	7.40	4	13.50
Dietician consultations			2	10.20		
Laboratory assessments	2	17.28	1	91.42	2	34.60
Food substitutes (daily meals)			56	2.09	180	1.92
Medications/vitamins/chew (daily dosage)					90	0.24
Annual follow-up—years 2 through 5						
Physician consultations	3	4.18	4	12.91	1	40.95
Laboratory assessments	2	17.28	1	91.42	1	34.60
Total year 1	€ 29.82		€ 310.10		€ 582.59	
Total annual follow-up—years 2 through 5	€ 29.82		€ 47.51		€ 75.55	
Cumulative discounted—annual 3.5%	€ 134.64		€ 468.22		€ 831.01	

described elsewhere [3]. The model (Microsoft™ Excel™) structure with its calculation algorithms and eight output variables, the peer-reviewed literature clinical and epidemiological inputs to the model, and the assumptions made regarding base case and worst-case scenarios for clinical effectiveness and safety are those described in that previous publication [3].

The base case scenario is derived from average reported BMI reduction and T2DM improvement in the reviewed publications. It defines CT as the continuation of medically guided diet during 1 year in spite of previous failure, followed by 4 years of watchful waiting. It also considers the average payer-perspective costs according to available sources. The worst-case scenario was conducted as an alternative to sensitivity analysis. It assumes that AGB and GBP were about 20% less effective in terms of BMI reduction and T2DM remission than in the literature-supported base case and that CT was low-cost watchful waiting only, with no BMI reduction and no T2DM remission at all during 5 years. The annual cost of treating T2DM is assumed to be the same as in the base case. The methods for gathering payer-perspective cost inputs for GBP and AGB, CT, and T2DM treatment are also the same as previously reported [3, 4].

Clinical evidence was obtained from the literature. Resource utilization data in AGB, GBP, and CT were obtained from quoted publications so as to reflect practice in 2009. A comprehensive list of health care resources necessary for preoperative assessment, laparoscopic GBP and AGB surgical operations, follow-up, and the treatment of complications up to 5 years after surgery was established in Austria, Italy, and Spain by the authors. The payer-perspective cost of CT in each country was based on a review of resource use known to be covered by payers. Unit costs were obtained from published sources when available or from coauthors' institutions otherwise.

Cost inputs for AGB and GBP initial hospital admission in 2009 are: the Lombardy diagnostic-related group (DRG) tariff in Italy, the average service-based hospital tariff (Leistungsorientierte Krankenanstaltenfinanzierung, LKF) in Austria, and microcosting estimates from two hospitals in Madrid (Hospital Clinico "San Carlos" and Fundación

Table 4 Base case input—average cost of T2DM per patient—estimates for 2009

	Austria (€)	Italy (€)	Spain (€)
Total annual	3,440.00	3,805.39	1,661.60
Ambulatory care	619.00	706.11	424.94
Antidiabetic medications	223.00	80.15	77.61
Other medications	706.00	745.56	628.51
Hospital care	1,892.00	2,273.56	530.54
Total over 5 years (3.5% discount rate)	15,531.78	17,181.52	7,502.20

Table 5 Base case output: BI and incremental cost-effectiveness ratios

Over 5years	Austria	Italy	Spain
AGB *vs.* CT in patients with 100% T2DM at baseline			
Budget impact in 1,000 patients (million €)	−2.942	−1.107	1.497
ICER: €/QALY	−2,861	−1,077	1,456
ICER: €/BMI year	−50.9	−19.2	25.9
ICER: €/T2DM-free-year	−1,201	−452	611
GBP vs. CT in patients with 100% T2DM at baseline			
Budget impact in 1,000 patients (million €)	−1.938	−1.670	3.570
ICER: €/QALY	−1,447	−1,246	2,664
ICER: €/BMI year	−24.0	−20.7	44.2
ICER: €/T2DM-free-year	−740	−637	1,362

Hospital Alcorcón) in Spain. To these inputs are added the cost of preoperative assessment, complications, and follow-up over 5 years (Tables 1 and 2).

Cost of CT in Spain is based on a peer-reviewed study comparing two low-calorie diets (Table 3) [5]. This modeling work used the less costly of the two diets because the authors report it to be as effective as and safer than the more expensive one, as well as more cost-effective. In Austria, payers do not currently fund diets, so the cost of CT from a payer perspective is defined as simple annual medical checkup. In Italy, no published source on the cost of CT has been identified in a systematic search, while CT is confirmed to be funded by the health care payers of some regions. Italian health economists and government health policy makers frequently use HTA reports published by the National Institute for Clinical Excellence to derive conclusions applicable to the Italian National Health System [6–8]. Therefore, the cost of CT in the Italian model is based on the assumption that resources for CT in England's National Health Service used in the UK model are applicable and can be combined with published Italian outpatient care unit tariffs for 2009 or, in their absence, with cost estimates made by the Italian coauthors based on their recent experience [9].

Cost inputs for T2DM management in Italy and Spain are obtained from the CODE-2 publication, but given that the nominal cost of treating T2DM steadily increased due to inflation and other factors, costs provided are inflated using a 3.5% annual compound rate from 2002 through 2009 (Table 4) [4]. The 3.5% rate was used in the previous publication and is still applied given recommendations by various European health economic methodological references [10–13]. This rate both reflects inflation as well as the progressive increase in resource utilization over time to treat the same disease. Since CODE-2 or similar studies have not been conducted in Austria, the cost of T2DM is estimated on the assumption that average European proportions reported in CODE-2 can be combined with Austrian aggregate public health spending and T2DM prevalence data. Total annual health care expenditure attributable to T2DM reported in CODE-2 is 5%. In Austria, given an estimated T2DM prevalence of 320,000 patients, a total public health care spending of 19.956 billion euros in 2006, and a 3.5% annual compound

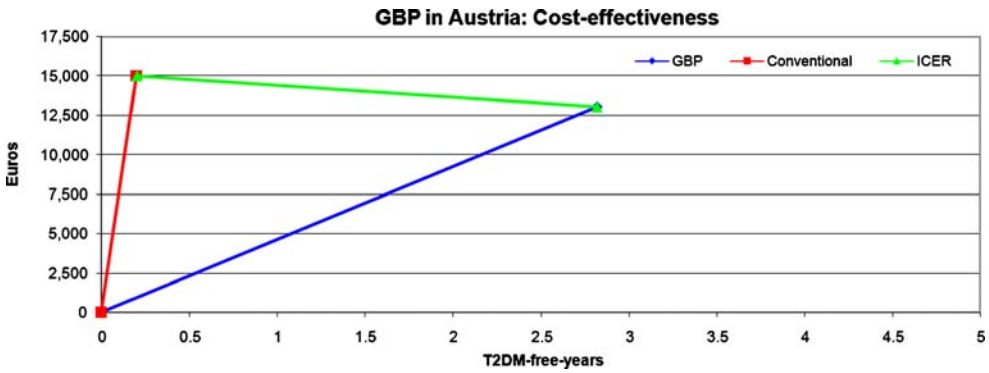

Fig. 1 Cost-effectiveness in €/T2DM-free-year—GBP—BMI≥35 kg.m^{-2} with T2DM—Austria

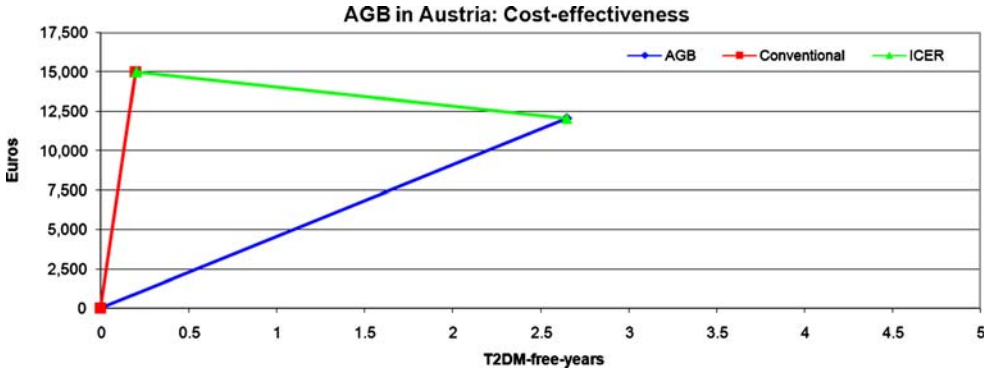

Fig. 2 Cost-effectiveness in €/T2DM-free-year—AGB—BMI≥35 kg.m^{-2} with T2DM—Austria

increase, T2DM annual cost per patient in 2009 is estimated at 3,440€ [14–16].

Overall, estimated payer-perspective cost inputs over 5 years in Austria are 15,532€ for T2DM management, 135€ for CT, 4,785€ for AGB, and 6,361€ for GBP. In Italy, these numbers are 17,182€ for T2DM management, 468€ for CT, 7,759€ for AGB, and 7,831€ for GBP. In Spain, these numbers are 7,502€ for T2DM management, 831€ for CT, 5,995€ for AGB, and 8,344€ for GBP. The incremental cost-effectiveness ratio (ICER) between two treatments is graphically represented as the slope of their cost difference divided by their difference in effectiveness. Effectiveness can be quantified in terms of direct clinical characteristic or as utilities expressed in "quality adjusted life-years" (QALYs). "Willingness to pay" (WTP) is defined by health economists as the cutoff level of ICER above which incremental effectiveness becomes too expensive and under which it is acceptable health value for money. WTP thresholds reported for European payers are usually between 30,000 and 50,000€/QALY [12, 13, 17]. This work used the more conservative value of 30,000€/QALY. The BI is the cost difference between two treatment options multiplied by the number of cases.

Results

Clinical outcomes calculated by the model over the 5-year horizon are the same as previously described: annual BMI variation, annual T2DM prevalence variation associated to the use of antidiabetic drugs, and treatment complications up to 5 years after bariatric surgery GBP/AGB or CT [3].

BI and incremental cost-effectiveness ratios are computed taking into account these clinical outcomes.

Base Case Scenario over 5 Years BI compared to CT in 1,000 patients all presenting a baseline T2DM is −2.942 million euros for AGB and −1.938 million euros for GBP in Austria, −1.107 million euros for AGB and −1.670 million euros for GBP in Italy, and 1.497 million euros for AGB and 3.570 million euros for GBP in Spain. The ICERs in

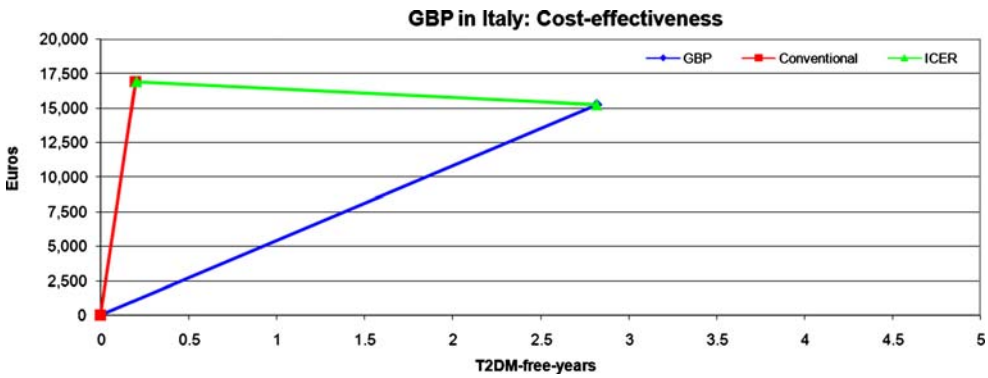

Fig. 3 Cost-effectiveness in €/T2DM-free-year—GBP—BMI≥35 kg.m^{-2} with T2DM - Italy

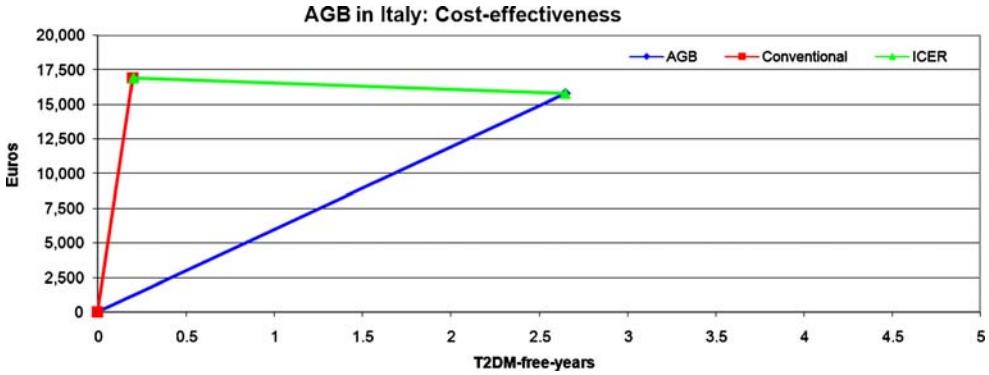

Fig. 4 Cost-effectiveness in €/T2DM-free-year—AGB—BMI≥35 kg.m^{-2} with T2DM—Italy

Austria are −2 861€/QALY and −1 201€/T2DM-free-year for AGB and −1 447€/QALY and −740€/T2DM-free-year for GBP. In Italy, these numbers are −1,077€/QALY and −452€/T2DM-free-year for AGB and −1,246€/QALY and −637€/T2DM-free-year for GBP. In Spain, these numbers are 1,456€/QALY and 611€/T2DM-free-year for AGB and 2,664€/QALY and 1,362€/T2DM-free-year for GBP. Base case scenario results are summarized in Table 5 and in Figs. 1, 2, 3, 4, 5, and 6.

Worst-case Scenario over 5 Years Conducted as an Alternative to Sensitivity Analysis BI compared to CT in 1,000 patients all presenting a baseline T2DM is −1.238 million euros for AGB and −0.335 million euros for GBP in Austria, 0.548 million euros for AGB and 0.105 million euros for GBP in Italy, 2.710 million euros for AGB and 4.834 million euros for GBP in Spain. ICER in Austria is −1 680€/QALY and −741€/T2DM-free-year for AGB and −301€/QALY and −159€/T2DM-free-year for GBP. In Italy, these numbers are 638€/QALY and 281€/T2DM-free-year for AGB and 94€/QALY and 50€/T2DM-free-year for GBP. In Spain, these numbers are 3,142€/QALY and 1,390€/T2DM-free-year for AGB and 4,347€/QALY and 2,302€/T2DM-free-year for GBP. Worst-case scenario results are summarized in Table 6.

Discussion

Methodological aspects and clinical inputs are previously discussed, and this discussion focuses on these three countries' health economic aspects. Sensitivity analysis is very important as payer-perspective costs vary greatly within each country. Fluctuations in the cost of T2DM and CT are also considerable depending on the area. As regards the average annual cost of T2DM in Italy and Spain, sensitivity analysis should be conducted on the full range reported by the CODE-2 study. Similarly, sensitivity analysis on a similar range should be applied to the estimate calculated for Austria.

Austria The LKF point value of 0.75€ is chosen as a point estimate for the base case, but sensitivity analysis should be conducted on its nationwide range which is roughly between 0.5 and 1€. Sensitivity analysis should also include

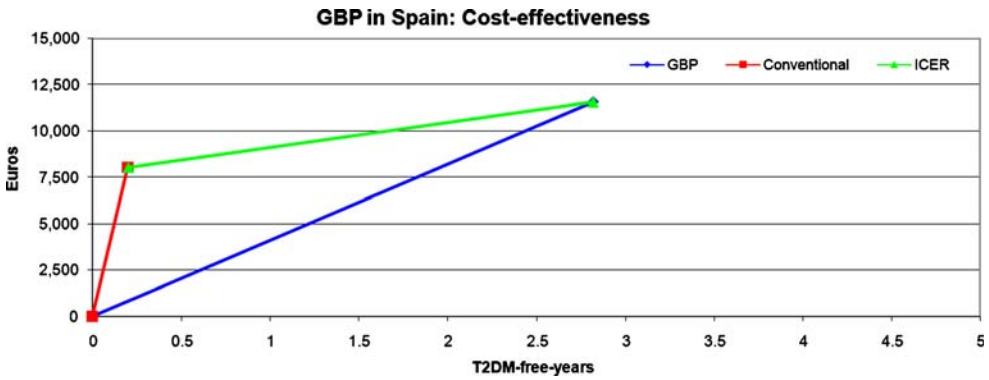

Fig. 5 Cost-effectiveness in €/T2DM-free-year—GBP—BMI≥35 kg.m^{-2} with T2DM—Spain

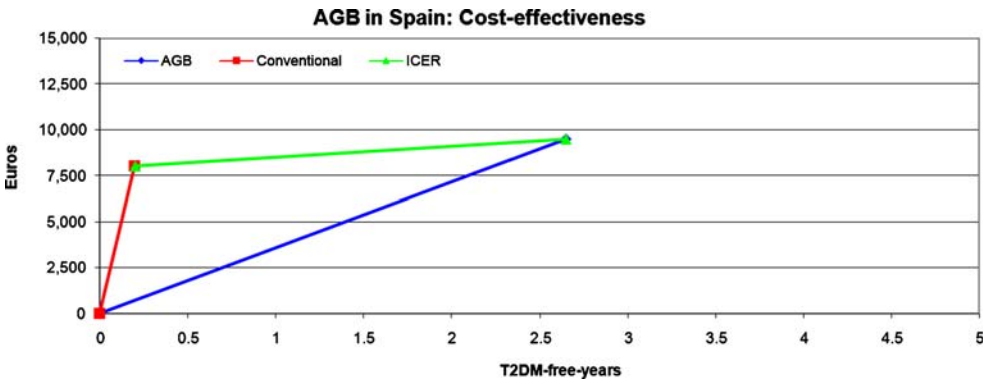

Fig. 6 Cost-effectiveness in €/T2DM-free-year—AGB—BMI≥35 kg.m^{-2} with T2DM—Spain

days in intensive care unit. A prospective study using a methodology compatible with CODE-2 would be needed to confirm the Austrian model.

Italy The tariff for DRG 288 varies across regions and types of institutions with lows around 2,852€ in Basilicata and highs reaching 7,281€ in certain hospitals of Tuscany. The DRG tariff applicable in Lombardy is used because it is the region where most bariatric procedures are conducted.

Spain Central government uses DRG 288 for nationwide count of obesity surgery, but this is not used to fund individual bariatric procedures. Funding in most hospitals reflects the amount spent within the annual budget plan and is therefore variable with the institution's cost structure. The annual cost of T2DM derived from CODE-2 increased by a compound 3.5% rate is close to amounts reported by other Spanish studies [18].

Conclusion

The deterministic model can be applied to countries where details of the cost of AGB, GBP, CT, and T2DM are available or can be estimated over a 5-year horizon. The base case shows that AGB and GBP in patients with baseline T2DM, compared to CT, are cost-saving in Italy and in Austria and moderately cost-increasing but cost-effective in Spain. Under worst-case scenario, AGB remains cost-saving, while GBP is about break-even in Austria; AGB and GBP are about breakeven in Italy, and AGB and GBP still lead to a cost increase with satisfactory cost-effectiveness in Spain, assuming a willingness-to-pay threshold of 30,000€/QALY. Thus, compared to CT, AGB and GBP are not only clinically effective and safe but also represent satisfactory value for money from a payer perspective in these three countries.

Table 6 Worst-case analysis in T2DM patients: 20% less effective AGB and GBP vs. CT

Over 5years	Austria	Italy	Spain
AGB vs. CT in patients with 100% T2DM at baseline			
Budget impact in 1,000 patients (million €)	−1.445	0.548	2.710
ICER: €/QALY	−1,680	638	3,142
ICER: €/BMI year	−25.9	11.2	55.1
ICER: €/T2DM-free-year	−741	281	1,390
GBP vs. CT in patients with 100% T2DM at baseline			
Budget impact in 1,000 patients (million €)	−0.335	0.105	4.834
ICER: €/QALY	−301	94	4,347
ICER: €/BMI year	−5.0	1.5	71.6
ICER: €/T2DM-free-year	−159	50	2,302

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Dr Giuliano Romagnoli: none

Pr Antonio Torres: none

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