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Impact of endoscopic ultrasound-guided gallbladder drainage on reducing costs of reintervention and unplanned readmission: a budget impact analysis

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ABSTRACT

Background and study aims Endoscopic ultrasound-guided gallbladder drainage (EUS-GBD) is the preferred treatment for patients with acute calculous cholecystitis who are unfit for surgery. The aim of this study was to perform a cost-effective analysis (CEA) comparing EUS-GBD with percutaneous gallbladder drainage (PT-GBD).

Patients and methods CEA was performed on patients recruited for our prior randomized controlled trial. A budget impact model was developed to compare the base-case and scenario of EUS-GBD applications. The costs including peri-procedure and intra-procedure, reinterventions, expenses associated with treatment of adverse events (AEs), costs of hospital stay, subsequent clinic follow-up, and unplanned readmission were included.

Results PT-GBD had a lower total procedure cost per patient (USD$4,375.00) than EUS-GBD (USD$9,397.44). For EUS-GBD, the cost of cautery-enhanced lumen-apposing stent accounted for the major part of the expense (USD $4,910.26). EUS-GBD resulted in a lower expected cost (USD$108.26 vs USD$1,601.54) for a re-procedure. The expected cost per patient in unplanned readmissions in the EUS-GBD group (USD$450.00) was lower than that in the PT-GBD group (USD$1,717.56). Based on the budget impact analysis, the net budget impact per year of introducing EUS-GBD to replace PT-GBD was higher (USD $16,424.10 vs USD$11,433.08). The net budget impact was most sensitive to the cost of stent and linear echoendoscope used in EUS-GBD.

Conclusions The net budget impact per year was higher for introducing EUS-GBD. The cost of the stent accounted for the major cost difference between the two procedures. EUS-GBD saved on the cost in management of AEs, reinterventions, and unplanned readmissions but these did not offset the cost of the stent.

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Introduction

In a previous multicenter randomized controlled trial (RCT) comparing EUS-guided gallbladder drainage (EUS-GBD) with percutaneous gallbladder drainage (PT-GBD) in patients who were at very high risk for cholecystectomy, our group showed that EUS-GBD significantly reduced 1-year adverse events (AEs) (25.6 % vs 77.5 %, $P<0.001$), 30-day AEs (12.8 % vs 47.5%, $P=0.001$), reinterventions after 30 days (2.6 % vs 30 %, $P=0.001$), number of unplanned readmissions (15.4 % vs 50 %, $P=0.002$) and recurrent cholecystitis (2.6 % vs 20 %, $P=0.029$) [1]. We then concluded that EUS-GBD and PT-GBD had similar rates of serious AEs but EUS-GBD improved outcomes and should be the procedure of choice in patients unfit for cholecystectomy. Similar findings were also demonstrated in several systematic reviews and network meta-analysis supporting the application of EUS-GBD [2–5]. However, EUS-GBD requires specialized trained personnel and dedicated devices that are expensive, and whether the procedure is cost-effective in managing the previously described patient group after considering factors such as healthcare cost and subsequent health service utilization is uncertain. Hence, the aim of the current study was to perform a cost-effectiveness analysis (CEA) comparing EUS-GBD with PT-GBD, based on data from patients recruited to the previous RCT.

Patients and methods

A CEA was performed involving patients recruited for a prior RCT that compared the outcomes of EUS-GBD versus PT-GBD in treatment of acute calculous cholecystitis in patients at very high risk for cholecystectomy in a randomized multicenter setting [1]. Only patients who were recruited at the Hong Kong site were included in this study to prevent differences in health care costs in different countries from affecting the outcomes of the CEA.

Study protocol

Details of the original RCT were previously reported [1]. In brief, after randomization, patients were scheduled to receive either EUS-GBD or PT-GBD within 4 to 6 hours. EUS-GBD was performed using a cautery-enhanced lumen-apposing metal stent (LAMS) (Hot AXIOS, Boston Scientific Medical Corporation, Marlborough, Massachusetts, United States) via the duodenum or stomach. The primary outcome measurement was the cumulative rate of AEs in 1 year. Secondary outcomes include technical and clinical success, daily post-procedure pain scores for the first 7 days, analgesic requirements, unplanned readmissions, and reinterventions. Patients were followed for up to 1 year.

Budget impact model

A budget impact model was developed to compare the budget impact between the base-case and scenario of EUS-GBD applications. The time horizon of the model analysis was 1 calendar year (i.e. 2018) and because of this short duration, no discounting of costs was applied. All costs were expressed in US dollars (1.0 US$ = 7.8 HK$) using 2018 as the fiscal year. In the base-case, we assumed the scenario in which only a typical PT-GBD procedure was available, whereas in a testing scenario, we assumed EUS-GBD was available to all non-surgical patients with acute cholecystitis. In the model, the sample size for patients receiving the gallbladder drainage procedures was estimated based on historical records of hospital admissions from the Hospital Authority of Hong Kong. Information on medical cost was retrieved from standard prices in private hospitals in Hong Kong. The expected net budget impact of EUS-GBD was calculated as the difference in total costs for the target population between these two scenarios.

Study population

The size of the study population was estimated using surgical records from all public hospitals in Hong Kong in 2018. Of a total of approximately 20,000 elective cholecystectomies, about 2 % of the procedures involved patients that received operations for acute cholecystitis who underwent PT-GBD before cholecystectomy. A hypothetical population size of 400 (out of 7.3 million) was thus assumed in our study.

Costs required before gallbladder drainage procedures

Blood tests and medical imaging were required for patients with acute calculous cholecystitis before the surgical procedures. Blood testing included complete blood count, liver function test, amylase test, renal function test, clotting profile, and type and screen, whereas medical imaging included ultrasound scan, computed tomography (CT) scan, and chest and abdominal x-rays.

Costs of gallbladder procedures and post-procedures

Equipment costs were required for EUS-GBD and PT-GBD procedures. In EUS-GBD, a linear echoendoscope and the LAMS were required; whereas in PT-GBD, drainage of the gallbladder with ultrasound guidance was needed. After the procedure, blood tests and medical imaging were performed, except type and screen during patient hospital stays. A follow-up endoscopy to check for stone clearance was required for patients receiving EUS-GBD, whereas a cholecystogram was required for patients receiving PT-GBD. Hospitalization costs were accounted for patients who had received the procedures.

Costs of clinical follow-up

The number of clinical follow-up visits via outpatient settings depended on the health status of a patient. The expected cost for required follow-up in each season (i.e. 3, 6, 9, and 12 months) was associated with a probability in the EUS-GBD and PT-GBD groups, respectively [1].

Costs of medications for treating adverse events

We determined the expected costs of medications as the product of the proportion of patients prescribed a specific medication and the unit cost for the medication using data from the previous multicenter trial [1]. Some additional items, such as

▶ **Table 1** Probabilistic inputs and corresponding 95 % CIs.

		Probabilistic inputs	95 % CI
EUS-GBD	Re-procedure	2.6 %	0 % to 7.52 %
	Clinical follow-up at month 3	72.4 %	56.1 % to 88.7 %
	Clinical follow-up at month 6	65.5 %	48.2 % to 82.8 %
	Clinical follow-up at month 9	34.5 %	17.2 % to 51.8 %
	Clinical follow-up at month 12	62.1 %	44.5 % to 79.7 %
	Unplanned readmissions	15.4 %	4.06 % to 26.7 %
PT-GBD	Re-procedure	30 %	15.8 % to 44. 2 %
	Clinical follow-up at month 3	70 %	53.6 % to 86.4 %
	Clinical follow-up at month 6	50 %	32.1 % to 67.9 %
	Clinical follow-up at month 9	30 %	13.6 % to 46.4 %
	Clinical follow-up at month 12	30 %	13.6 % to 46.4 %
	Unplanned readmissions	50 %	34.5 % to 65.5 %

CI, confidence interval; EUS-GBD, endoscopic ultrasound-guided gallbladder drainage; PT-GBD, percutaneous gallbladder drainage.

ciprofloxacin for treating urinary tract infections and enoxaparin for treating acute myocardial infarction, were required in the procedural groups.

Costs of unplanned readmission and additional items in re-procedures

Patients receiving EUS-GBD or PT-GBD would have a chance for unplanned readmission and those costs were included, accounting for the associated probability in either group. Patients would also have a risk for redoing the procedure and on top of costs of blood tests and medical imaging, cost items in stone clearance (extracorporeal shockwave lithotripsy of the gallbladder, basket, lithotripter, and rat-tooth forceps) and change of stent (permanent 7F double pigtail catheter) were required for EUS-GBD. According to our previous RCT, only three of 27 patients (11.1 %) required more than one cholecystoscopy; therefore, we assumed patients would not have more than one re-procedure in a single year.

Probability inputs

We obtained the probabilities for clinical follow-up, unplanned readmission, and re-procedures for both EUS-GBD or PT-GBD from the previous multicenter trial [1].

Sensitivity analysis

One-way sensitivity analyses were conducted to assess the impact of the assumed model parameters on the budget impact with a Tornado diagram. The probabilistic parameters for clinical follow-up, re-procedure, and unplanned readmissions by drainage group were varied using 95 % confidence intervals (CIs) reported in the multicenter trial (▶ **Table 1**) [1]. Cost parameters also varied by ± 20 %. Plausible ranges were assumed for parameters of medication use (**Appendix 1**).

Results

▶ **Table 2** summarizes the costs for blood tests, medical imaging, clinical follow-up, and medications. Before the procedures, blood tests and medical imaging were required for the patients with acute calculous cholecystitis and they accounted for $1,066.03 per patient in both groups. CT and ultrasound were two major cost items in the pre-procedure, priced at $352.56 and $314.10 per patient, respectively. When patients were admitted for the drainage procedures, PT-GBD had a lower total procedural cost per patient ($4,375.00) than EUS-GBD ($9,397.44) (▶ **Table 3**). For EUS-GBD, the cost of the cautery-enhanced LAMS (10 × 10 mm or 15 × 10 mm, Hot AXIOS, Boston Scientific Medical Corporation, Marlborough, Massachusetts, United States) accounted for the major part of its cost (i. e. $4,910.26). For a potential re-procedure, a total of $5,338.46 per patient was required for PT-GBD, whereas a total of $7,032.31 was required for EUS-GBD when stone clearance and change of stent also were required. Nevertheless, with a lower probability of re-procedure (i. e. 2.56 % vs 30 %), EUS-GBD resulted in a lower expected cost ($180.03 vs $1,601.54) in general.

With respect to the costs used in the post-procedure period, the expected cost of hospitalization was similar between the two groups of patients when the average duration of hospitalization was taken into account. The total post-procedure costs for EUS-GBD and PT-GBD were $5,078.85 and $2,458.97 per patient, respectively. Endoscopy of the biliary tract for a patency check accounted for the major cost item in EUS-GBD (i. e. $3,192.31). Because follow-up cholecystoscopy is not a universal practice, a one-way sensitivity analysis was conducted to omit scheduled endoscopy for stent removal. According to the results, the total expected cost per patient receiving EUS-GBD was slightly reduced to around $16,243.70, resulting in a

▶ **Table 2** Costs (in US$) for blood tests, medical imaging, clinical follow-ups, and medications.

	Items	Unit cost [source]
Blood test	Complete blood count	19.23 [11]
	Liver function test	66.67 [12]
	Amylase	25.00 [12]
	Renal function test	65.38 [12]
	Clotting profile	26.92 [12]
	Type & screen	102.56 [12]
Imaging	Ultrasound scan	314.10 [12]
	CT scan	352.56 [12]
	Chest x-ray	32.05 [12]
	Abdominal x-ray	61.54 [12]
Clinical follow-up	Outpatient follow-up at 3, 6, 9, and 12 months	41.03 [1, 12]
Medications	Midazolam 5 mg	0.52
	Diazepam emulsion 10 mg	5.96 [13]
	Pethidine 50 mg	0.54 [13]
	IV propofol	0.75 [13]
	IV amoxicillin clavulanate 1.2 g	0.77 [13]
	Oral amoxicillin clavulanate/Tab	0.09 [13]
	IV cefoperazone/sulbactam 1 g	0.67 [13]
	IV ciprofloxacin 400 mg	11.34 [13]
	Oral ciprofloxacin 250 mg	0.04 [13]
	IV levofloxacin 500 mg	5.16 [13]
	IV ceftriaxone 1 g	0.32 [13]
	IV piperacillin/tazobactam 4.5 g	1.98 [13]
	IV metronidazole 500 mg	0.63 [13]
	IV meropenem 500 mg	1.92 [13]
	IV ertapenem 1 g	15.98 [13]
	IV vancomycin 500 mg	1.63 [13]
	IV linezolid 600 mg	66.55 [13]
	IV tramadol 50 mg	0.16 [13]
	Oral paracetamol 500 mg	0.01 [13]
	Oral tramadol 50 mg	0.02 [13]
	Antibiotics (ciprofloxacin)	704.87 [13]
	Antibiotics/IV fluids	8.19 [13]
	IV fluids/inotropes (dobutamine 24, dopamine 33)	447.69 [13]
	Enoxaparin 10	71.87 [13]
	Antibiotics/antiarrhythmics/percutaneous drainage of collection	4991.18 [13]
	Fast AF/ARF/death	406.47 [13]

IV, intravenous; AF, atrial fibrillation; ARF, acute renal failure.

▶ **Table 3** Costs (USD) for EUS-GBD and PT-GBD procedures, re-procedures, and unplanned readmissions[1].

	EUS-GBD	PT-GBD
Equipment	Linear echoendoscope (endoscopy, including 19-gauge needle, and 0.025/0.035 guidewire): $4,487.18 [internal cost list] Hot AXIOS stent (10 × 10 mm)/(15 × 10 mm) including fluoroscopy, need of crossover, 8.5F/10F double pig-tail: $4,910.26 [Internal cost list, [3]	Percutaneous drainage of gallbladder with imaging guidance including 18-gauge needle, 0.035" guidewire, fluoroscopy, and bedside bag: 4,375.00 [internal cost list], [3]
Follow-up cholecysto-scopy	Endoscopy (endoscopy of biliary tract): 3,192.31 [Internal cost list]	Cholecystogram: $457.05 [14]
Hospitalization	Estimated to be 8 days on average with $115.38 per day [5, 6]	Estimated to be 9 days on average with $115.38 per day [1], [14]
Unplanned readmissions	Estimated to be 7 days on average with $417.88 per day [internal cost list], [6]	Estimated to be 8.22 days on average with $417.88 per day [internal cost list], [6]
Re-procedure	Extracorporeal shockwave lithotripsy of the gallbladder: $4,375.009 Basket: 435.38 [Internal cost list] Lithotripter: 243.59 [Internal cost list] Rat-tooth forceps: 982.82 [Internal cost list] Permanent 7F double pigtail catheter: 32.05 [internal cost list]	

EUS-GBD, endoscopic ultrasound-guided gallbladder drainage; PT-GBD, percutaneous gallbladder drainage.
[1] Cost was calculated according to private hospital charges in Hong Kong.

$0.07 million drop in the net budget impact when compared with the original results.

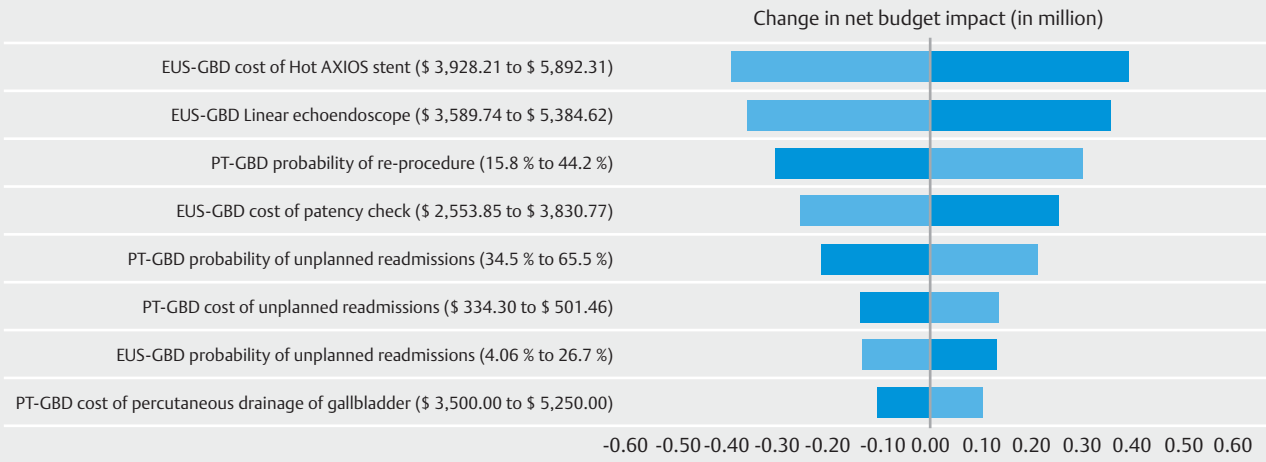
The cost for the trimonthly follow-up was similar between the two groups. Given a lower probability of unplanned readmissions for patients receiving EUS-GBD (15.4% vs 50%), the expected cost per patient in unplanned readmissions in the EUS-GBD group ($450.00) was lower than that in the PT-GBD group ($1,717.56). Given a reduction in relative frequency of AEs in the EUS-GBD group, the expected total costs for medications per patient was lower ($25.51) when compared with that in the PT-GBD group ($62.95). However, the medications only accounted for a minor proportion of costs over all the procedure items.

Based on the budget impact analysis, the net budget impact per year of introducing EUS-GBD to replace PT-GBD was higher. The total expected cost per patient receiving EUS-GBD was around $16,424.10, while the total expected cost per patient receiving PT-GBD was around $11,433.08. When the 400-patient local population per year was considered to have replacement with EUS-GBD, our analysis indicated that an incremental cost of $2.0 million was required. Assuming a local population size of 7.5 million, an incremental cost of $0.27 per inhabitant was required relative to the general population.

Uncertainty in budget impact was examined with a Tornado diagram (▶ **Fig. 1**). In general, our main result was robust when the assumed model parameters varied in the plausible ranges. The budget impact was most sensitive for LAMS and linear echoendoscope, the equipment for EUS-GBD. When the unit cost of LAMS was altered from $3,928.21 to $5,892.31, the net budget impact varied ±$0.39 million, whereas the unit cost of linear echoendoscope was altered from $3,589.74 to $5,384.62, the net budget impact varied ±$0.36 million. The probability of re-procedure for patients receiving PT-GBD was the third most sensitive parameter due to a higher likelihood of re-procedure compared with that in patients receiving EUS-GBD. Varying the cost of patency check from $2,553.85 to $3,830.77 would result in a change of ±$0.26 million in the net budget impact. Varying the cost and probability of unplanned readmission for patients receiving PT-GBD would generate changes of ±$0.14 and ±$0.21 million in net budget impact, respectively.

Discussion

We previously demonstrated in a RCT that EUS-GBD was associated with reduced 30-day and 1-year rates of AEs, reinterventions, unplanned admissions, and recurrent cholecystitis when compared with PT-GBD in very high-risk patients who could not undergo cholecystectomy [1]. In the present study, we assessed whether EUS-GBD was cost-effective as compared to PT-GBD. Our findings showed EUS-GBD could save the expected costs for re-procedure, medications for AEs, and unplanned readmissions. However, due to major cost items in equipment for LAMS and additional endoscopy to check for stone clearance in the EUS group, the net budget impact per year of introducing EUS-GBD to the PT-GBD was higher. The total expected cost per patient receiving EUS-GBD was around $16,424.10, while the total expected cost per patient receiving PT-GBD was around $11,433.08. Reducing the cost of LAMS for EUS-GBD to < $100 would almost result in a zero net budget impact per year, which is not a plausible consideration. However, we speculate that EUS-GBD is likely to generate a cost-effective result if the gain in quality of life (QOL) owing, to a decreased chance of re-procedure, medications needed for AEs, and unplanned readmissions are taken into consideration. This warrants further investigations.



▶ **Fig. 1** Tornado diagram: result of univariate sensitivity analyses. Key assumptions were ranked by influence on net budget impact and each horizontal bar indicates the uncertainty range on the budget impact. Only assumptions influencing more than a range of ±0.1 million are listed.

EUS-GBD is gaining popularity as an alternative to PT-GBD for gallbladder drainage in patients suffering from acute cholecystitis who are at very high risk for cholecystectomy. Echoing the findings of our RCT, several other comparative studies have shown that EUS-GBD is associated with multiple advantages over PT-GBD, including reduced pain scores, AEs, unplanned admissions, and reinterventions [6–9]. A subsequent network meta-analysis compared endoscopic transpapillary gallbladder drainage (ETP-GBD), EUS-GBD, and PT-GBD [3]. The study concluded that EUS-GBD was associated with higher rates of clinical success with lower rates of recurrent episodes of cholecystitis, while ETP-GBD was associated with lowest rates of reintervention, unplanned admissions, and mortality. PT-GBD was associated with high rates of technical success but it was also associated with the highest rates of subsequent interventions and unintended hospitalizations. Hence, in patients who are potential surgical candidates, ETP-GBD is preferred over PT-GBD. In patients who are not scheduled for cholecystectomy due to poor premorbid status, EUS-GBD is preferred over PT-GBD as a definitive treatment.

On the other hand, studies assessing the cost-effectiveness of modalities for gallbladder drainage based on randomized data are lacking. Corral et al reported the cost-effectiveness of EUS-GBD drainage based on a hypothetical retrospective cohort of poor surgical candidates [10]. This CEA was based on the results of a retrospective study comparing ETP-GBD, EUS-GBD and PT-GBD. In the three-way study, the PT-GBD group had a statistically significantly higher number of complications as compared to the EUS-GBD and ETP-GBD groups (20 % vs. 2 % vs. 5 %; $P = 0.01$). Mean hospital stay in the EUS-GBD group was significantly less than for ETP-GBD and PT-GBD (16 vs. 18 vs. 19 days; $P = 0.01$), while the required number of additional surgical interventions was significantly higher in the PT-GBD group in comparison with the EUS-GBD and ETP-GBD groups (49 % vs. 4% vs. 11 %; $P < 0.0001$). There is a significant risk of potential bias in this report, as a significant proportion of patients were still surgical candidates and the study outcome parameters may not be fully reported due to the retrospective nature of the study. Nevertheless, in the CEA, the authors reported that ETP-GBD was a cost-saving strategy and EUS-GBD was cost-effective, resulting in $1312 per hospitalization day averted. When compared to ETP-GBD, EUS-GBD required expending an additional $8950 to prevent one additional day of hospitalization. The authors concluded that endoscopic GBD is cost-effective compared to PT-GBD, favoring ETP-GBD over EUS-GBD.

There are a number of strengths and limitations to the current study. In terms of strengths, the budget impact data obtained in the current study were obtained from a RCT with well-defined inclusion and exclusion criteria and detailed collection of outcome parameters. Thus, the current study could be considered representative of real-life costs involved in management of these patients. Furthermore, only patients recruited in the Hong Kong center were included, thus the costs presented are not subject to variations in healthcare costs in different countries. Regarding limitations, because most of the patients recruited to the previous RCT were old and frail, they could not complete questionnaires on QOL and a CEA on use of EUS-GBD with regard to improvements in QOL could not be performed. In addition, the costs of health care may be different across different countries, and the generalizability of the findings may be limited. Also, the cost of cautery-enhanced LAMS accounted for the major cost difference when the procedure cost was budgeted. Thus, in time with increasing availability of these stents from different companies, the costs of the stents are likely to decrease, which may affect the budget analysis if the study is repeated in a few years. Moreover, a follow-up cholecystoscopy at 1 month in the EUS-GBD group is not a routine practice in some centers around the world, and hence, this procedure cost may not be applicable to them. Finally, the follow-up period was for 1-year AE rates and unplanned readmissions. This may not be long enough to review long-term complications of stone recurrence or stone-related complica-

tions. However, patient who participated were not candidates for surgery and had a mean (S.D.) age-adjusted Charlson Comorbidity Index of 5.6 (1.6). The survival of these patients was expected to be short.

Conclusions

In conclusion, the net budget impact per year on introducing EUS-GBD was higher. The cost of the stent accounted for the major cost difference between the two procedures. EUS-GBD could save costs in management of AEs, reinterventions, and unplanned readmissions, but that did not offset the cost of the stent. These advantages may have improved patient QOL, but that could not be assessed in the current study.

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Competing interests

Prof. Teoh is a consultant for Boston Scientific, Cook, Taewoong, and Microtech Medical Corporations.

Clinical trial

ClinicalTrials.gov
NCT02212717
TRIAL REGISTRATION: NCT02212717. RCT at http://www.clinicaltrials.gov/

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