

A pilot study of a natural fiber complex IQP-AK-102's effect in reducing appetite and caloric intake in overweight subjects

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ABSTRACT

A proprietary fiber complex, IQP-AK-102, consisting of glucomannan, kappa-carrageenan and xanthan gum, has been shown to reduce body weight in a double-blind, randomised, placebo-controlled clinical trial. It was postulated that IQP-AK-102 promotes weight loss through enhancing satiety, increasing gastric distension and delaying gastric emptying. Therefore, the aim of this study was to examine if appetite reduction through above-mentioned mechanisms is underlying the efficacy of IQP-AK-102 for body weight loss. Thirty-six healthy overweight adults (BMI 25-30 kg/m²) were administered 2 capsules of IQP-AK-102 three times daily for 4 weeks, after a 2-week run-in phase. Visual analogue scales (VAS) and Haber (hunger/satiety) scale were used to evaluate the appetite sensation. All measurements were assessed 3 days a week during the run-in phase as well as in the first and last week of the treatment period. The scales were completed before breakfast (at time -30 and 0 min) and after breakfast (at time 15, 30, 45, 60, 90, 120 and 180 min). Additionally, food intake was also recorded in a food diary. The appetite evaluation study showed that IQP-AK-102 reduced both the appetite sensation and the mean daily caloric intake significantly after 1 week and 4 weeks of intake. IQP-AK-102 was well tolerated throughout the study duration, with no product related adverse effects reported. These results suggest that IQP-AK-102 reduces appetite and caloric intake and thus, can be considered a natural and safe intervention for promoting weight loss.

Keywords: IQP-AK-102, dietary fiber, appetite reduction, satiety, obesity, weight loss.

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INTRODUCTION

The prevalence of overweight and obesity has been increasing worldwide over the past decades, affecting men and women of all ages. According to the 2016 Global Health Observatory report by the World Health Organization, about two billion adults worldwide are overweight, of which, more than half a billion are obese. Meanwhile, a systematic evaluation of the health effects of high body mass index (BMI) indicated that excess body weight accounted for about 4 million deaths and 120 million disability-adjusted life-years worldwide in 2015 (The GBD 2015 Obesity Collaborators, 2017). In addition, it has also been reported that obesity is among

the top three global social burdens. The worldwide economic toll due to obesity (including loss of productivity, direct costs for healthcare and investment to mitigate the disease) amounts to approximately two trillion US dollars; this amount is similar to that caused by smoking (Dobbs et al., 2014).

Proximally, the cause of the rising prevalence of obesity is a growing imbalance between energy intake and energy expenditure, while distally, the causes of obesity are also attributed by behavioral and environmental factors that may spur energy intake or depress energy expenditure (Harnack and Schmitz,

2010). Targeting negative energy balance via lifestyle interventions such as exercise, reduced food and calorie intake, and healthy food choices serve as first steps towards effective weight management. However, lifestyle intervention particularly dietary restriction is an uphill task in an ubiquitous obesogenic environment that encourages overeating (Dulloo, 2012; Mata et al., 2017). For example, the portion sizes of many foods and snacking frequency in the United States has been increasing since 1970 (Ello-martin et al., 2005; Piernas and Popkin, 2010). Besides, energy-dense processed food is easily available whilst such food is presumably high in fat and sugar and has a poor satiating value (Cassady et al., 2012; De Graaf, 2011). Therefore, appetite regulation has been proposed as one of the key measures to alleviate obesity. Currently, bariatric surgery (such as gastric band and gastric balloon) and anti-obesity drugs (such as lorcaserin, phentermine-topiramate and liraglutide) are available as treatment options for obese and overweight adults with comorbidities. However, patients undergoing treatment with anti-obesity drugs often experience drug-related side-effects (Kang and Park, 2012). Meanwhile, satiety promoting dietary supplements made from natural products such as fibers (e.g. grains, legumes, vegetables and oat) and botanical extracts (e.g. *Garcinia cambogia* extract) are widely available as non-pharmacological interventions, but often lack clinical data to support their efficacy (Burton-Freeman, 2000; Onakpoya et al., 2011).

There is scientific evidence that increased consumption of dietary fiber promotes satiety, decreases hunger and provides a feeling of fullness, ultimately leading to a reduced calorie intake and weight loss. Howarth et al. (2001) concluded that when energy intake is *ad libitum*, the consumption of an additional 14 g/day fiber for more than 2 days is associated with 10% decrease in energy intake and body weight loss of 1.9 kg over 3.8 months.

Water-soluble dietary fibers composed of polysaccharides such as pectins and mucilages are known to absorb large amounts of water. These fibers form a viscous, gel-liked material in aqueous solutions (Wursch and Pi-Sunyer, 1997) and appear to be effective in promoting satiety, compared to insoluble fibers (Slavin and Green, 2007). It was suggested that the bulking effect of viscous fibers in the stomach could prolong the gastric distension and increase the feeling of satiety (Bergmann et al., 1992). These findings were later confirmed by an in vivo imaging study through the magnetic resonance imaging (MRI), which demonstrated that a gel lump formed in the stomach contributed to the enhanced feeling of fullness (Hoad et al., 2004). The gel matrix formed by soluble fiber prolongs gastric emptying (Howarth et al., 2009), and delays nutrient absorption, glucose absorption in particular (Yu et al., 2014).

IQP-AK-102 (also known as Redusure™) is a proprietary, patent pending fiber complex that comprises glucomannan, kappa-carrageenan and xanthan gum. All these ingredients are high molecular weight

polysaccharides. Glucomannan is a soluble dietary fiber derived from the tuberous roots of *Amorphophallus konjac* K. Koch. Indigenous to Asia, glucomannan is classified as generally recognized as safe (GRAS) in the USA, as well as authorized as food additive in the EU (E425). Being one of the most viscous dietary fiber, glucomannan has the ability to absorb up to 50 times its weight in water (Doi, 1995). This results in the formation of a viscous gel that may delay gastric emptying and slow glucose delivery to the intestinal mucosa, thereby reducing dietary calories uptake and resulting in promotion of satiety, reduction of hunger and ultimately leading to weight loss (Keithley and Swanson, 2005; European Food Safety Authority, 2010; Mccarty, 2002). Similarly, both kappa-carrageenan and xanthan gum are of natural origin, recognized as food additives and widely used in food and drug industry as stabilizers, thickeners, and gelling agents. Unlike glucomannan, the research on health benefits of kappa-carrageenan and xanthan gum remains preliminary, however, a combination of these dietary fibers has been shown to result in a synergistic increase in the viscosity and gelling properties (Fitzpatrick et al., 2013; Kohyama et al., 1993; Kohyama et al., 1996; Takigami, 2009; Parry, 2010).

A randomized, placebo-controlled clinical study performed by Bongartz et al. (2016) has shown that IQP-AK-102 intervention significantly reduced the body weight of overweight healthy adults compared to placebo after 12 weeks by 3.53 (SD 2.28) kg and 0.14 (SD 1.84) kg, respectively ($p < 0.001$). Based on the study outcome, it was postulated that the fiber components of IQP-AK-102 are responsible for the observed weight loss, whereby the fiber components of IQP-AK-102 act synergistically by swelling in aqueous conditions, forming a thick, viscous, and indigestible gel matrix, which slows gastric emptying by modulating intestinal contractile activity (Samaan, 2017; Bongartz et al., 2016). Said mechanism could be responsible for inducing a feeling of satiety or fullness and thus ultimately promoting weight loss. Therefore, the purpose of this clinical study was to examine the efficacy of IQP-AK-102 in promoting satiety and reduction of appetite in otherwise healthy overweight subjects.

MATERIALS AND METHODS

Subjects

In this study, 36 overweight subjects including 13 males and 23 females (BMI 25-30 kg/m² and aged between 18 and 65 years) were recruited. Eligibility criteria included generally good health, regular daily consumption of 3 main meals (breakfast, lunch and dinner), regular physical activity (≤ 4 hours of strenuous sportive activity per week) and willingness to maintain the same level of physical activity throughout the study, consent to refrain from the use of other weight management products or programs during the study period, and presenting with stable body weight for the last 3 months prior to inclusion. Exclusion criteria were known sensitivity to the components of IQP-AK-102, bariatric surgery in the last 12

months, abdominal surgery within the last 6 months, active gastrointestinal diseases including stenosis in the gastrointestinal tract, malabsorption disorders, pancreatitis, history of eating disorders (bulimia, anorexia nervosa or binge-eating) within the last 12 months, lack of appetite with any (unknown) reason, gluten intolerance, alcohol consumption (≥ 21 units/week), smoking cessation within last 6 months, abuse of recreational drugs, alcohol or medications, and use of any medication that could influence body weight and gastrointestinal functions.

All subjects were provided with written informed consent. The study was approved by the ethics committee of the Charité–Universitätsmedizin Berlin and was performed based on the principles of the World Medical Association (Declaration of Helsinki, 2013), the ICH GCP guidelines (CPMP/ICH/135/95)/ICH E6 (R1) and the DIN EN ISO 14155. In addition, the clinical trial was registered at clinicaltrials.gov (NCT02774486).

Study intervention

This study was an open-label clinical trial, which was designed according to the guidance of the European Food Safety Authority for appetite ratings (European Food Safety Authority, 2012). It was conducted in Germany from April 2016 to August 2016.

The study comprised a 2-week run-in period and a 4-week treatment period. During the run-in period, subjects were required to record their calorie intake, satiety/hunger sensation, and physical activity for three days per week in a diary. Only subjects that adhered to the clinical investigation plan were eligible to be enrolled in the treatment phase.

Throughout the 4-week treatment period, subjects had to take two capsules of the investigational product 30 min before the three daily main meals (breakfast, lunch, and dinner) with a full glass of water (250 ml). The IQP-AK-102 dosage was similar to that given in the previous weight loss study (Bongartz et al., 2016). The IQP-AK-102 capsules were manufactured by InQpharm Europe Ltd. in a GMP certified facility in Germany. Each capsule contained 250 mg glucomannan powder, 150 mg kappa carrageenan, and 100 mg xanthan gum, as active ingredients. In order to simulate free-living conditions, there was no restriction on food and calorie intake. However, subjects were required to record their calorie intake, satiety/hunger sensation, and physical activities for three days per week in a diary. The physical activity level was assessed based on the International Physical Activity Questionnaire (IPAQ).

Outcome measures - efficacy

Changes in satiety/hunger sensation between baseline and week-1 and between baseline and week-4 of the treatment period were assessed by visual analogue scale (VAS). VAS is a 100-mm long line with words anchored at each end expressing the most positive and the most negative ratings for the assessment of four scores, hunger, satiety, fullness, and prospective food consumption (Gregersen et al., 2011). The Composite Satiety Score (CSS), was computed from the four individual scores as follows: $CSS = [\text{satiety} + \text{fullness} + (100 - \text{hunger}) + (100 - \text{prospective food consumption})/4]$. The area under the curve (AUC) was measured in millimeter x minutes, and derived from the CSS value by applying the trapezoidal rule:

$$AUC = \sum_{k=0}^7 (CSS_{k+1} + CSS_k) / 2 \cdot (T_{k+1} - T_k)$$

Changes in satiety and hunger sensations were also assessed by Haber scale, which comprises a 21-point scaling from -10 (different degrees of hunger) over "0" (no particular feeling) up to +10 (different degrees of satiety). All VAS and scales were completed 35 min before breakfast (at time -30 min), 5 min before breakfast (at

time 0 min) and 15, 30, 45, 60, 90, 120 and 180 min after breakfast on the assessment days. The assessments were performed on 2 weekdays and 1 weekend day during the first week and the fourth week (last week) of the treatment phase.

Other efficacy endpoints included changes in food intake based on the subject's food diary, changes in body weight and changes in waist and hip circumference.

Outcome measures - safety

Safety assessments included vital sign measurements such as heart rate and resting blood pressure and physical examination. In addition, safety and tolerability were documented in response to open questioning or based on spontaneous reporting by the subjects. All adverse events were recorded, regardless of their causality to treatment.

Statistical analysis

The sample size was determined based on the efficacy endpoint, that is, change in area under the curve (AUC) values. Based on an estimated difference of 10 mm (Flint et al., 2000), approximately 24 subjects were required to reach a sensitivity of 0.05 at a study power of 0.80 in a paired design. By taking into the consideration a 30% of dropout rate, a total of 36 subjects were included in the trial.

The statistical analysis was carried out in the Intention-to-Treat (ITT) population, which was defined as the number of all subjects enrolled in the study, who consumed at least one dose of IQP-AK-102. All endpoints were descriptively analyzed and checked for normality using Shapiro-Wilk test. Since the day per VAS score was known, a time-dependent effect was calculated. The results were analyzed via General Estimating Equations (GEE) model. Besides, depending on the distribution in the data the parameter-free Wilcoxon matched-pairs signed-rank-test or Kruskal-Wallis test was applied, in case of normality in the data a paired T-Test was applied. A *p*-value of 0.05 was used throughout the study applying two-sided testing. All values were presented as mean (standard deviation, SD) unless indicated otherwise. All data were analyzed using STATA Data Analysis and Statistical software, version 12 (Stata Corp, TX, US) and GraphPad Prism version 6 (GraphPad Software, Inc., CA, US).

RESULTS

Baseline characteristics of participants

The Intention-To-Treat (ITT) population comprised 35 subjects, with a mean age of 46.1 (SD 12.2) years and mean BMI of 28.0 (SD 1.28) kg/m². Most of the subjects were women (63.9%).

Effect of IQP-AK-102 on VAS scores (hunger, satiety, fullness, prospective food consumption (PFC))

There was a statistically significant difference in the change of CSS between baseline and after 1 week of treatment with IQP-AK-102, and as well between baseline and after 4 weeks of treatment. The individual parameters (hunger, satiety, fullness, and PFC) that make up the CSS were also significantly affected by the treatment with IQP-AK-102 (Table 1).

Table 1. Changes in mean AUC180 of the VAS scores (hunger, satiety, fullness, prospective food consumption (PFC)) between baseline and week-1, and between baseline and week-4 of treatment period.

Parameter	Baseline Mean (SD)	Week 1		Week 4	
		Mean (SD)	% change from baseline	Mean (SD)	% change from baseline
AUC180 of VAS Scores					
Hunger	8172.64 (2847.77)	6356.90 (2741.57)	-22.21*	6465.21 (2893.61)	-20.90*
Satiety	11973.80 (2480.77)	12967.60 (3842.45)	8.30*	13124.00 (3858.41)	9.61*
Fullness	11142.30 (2555.92)	12118.70 (4072.70)	8.76*	12404.30 (3779.12)	11.33*
PFC	9775.67 (3020.51)	7677.24 (3373.78)	-21.46*	7656.12 (3377.63)	-21.68*
CSS	12013.80 (2429.25)	13149.80 (3397.75)	9.46*	13280.20 (3427.01)	10.55*

AUC180: Area Under the Curve at time point T180; VAS: Visual Analogue Scale; PFC: Prospective Food Consumption; CSS: Composite Satiety Score; SD: Standard Deviation; all values were expressed as mean (SD); * $p < 0.001$ vs. Baseline.

Effect of IQP-AK-102 on hunger/fullness level and daily caloric intake

Evaluation of hunger/fullness level with Haber Scale also demonstrated statistically significant results at week-1 and week-4, in comparison to baseline. The changes of AUC of Haber Scale at week-1 [213.1 (SD 342.8), $p = 0.0016$] and week-4 [172.6 (SD 471.7), $p < 0.001$] had a p -value of < 0.001 compared to baseline. Besides, a statistically significant ($p < 0.01$) decrease in dietary energy intake was observed among the subjects. The results showed a decreased mean daily caloric intake after one week of IQP-AK-102 treatment [-195.3 (SD 440.1) kcal; $p = 0.0039$] as well as after four weeks of IQP-AK-102 treatment [-261.8 (SD 535.3) kcal; $p = 0.0019$] (Figure 1). The reduction of caloric intake during the treatment phase corresponds to a statistically significant reduction in body weight of -0.49 (SD 1.21) kg compared to baseline ($p < 0.05$) and a statistically significant reduction in waist and hip circumference [-0.7 (SD 1.4) and -0.6 (SD 1.1) cm respectively; both $p < 0.001$] after four weeks of IQP-AK-102 intake.

Safety

There were no clinically significant changes reported for heart rate and resting blood pressure before and after the treatment. At the end of the study, 97.2% of the subjects and investigators rated the tolerability of IQP-AK-101 as "very good". One adverse event (infection of upper respiratory airways) was reported in the course of the study. It was concluded by the investigators that the AE was not related to the intake of IQP-AK-102.

DISCUSSION

Based on the beneficial effect of soluble fibers on appetite regulation, IQP-AK-102 was formulated by combining three soluble fibers, namely glucomannan,

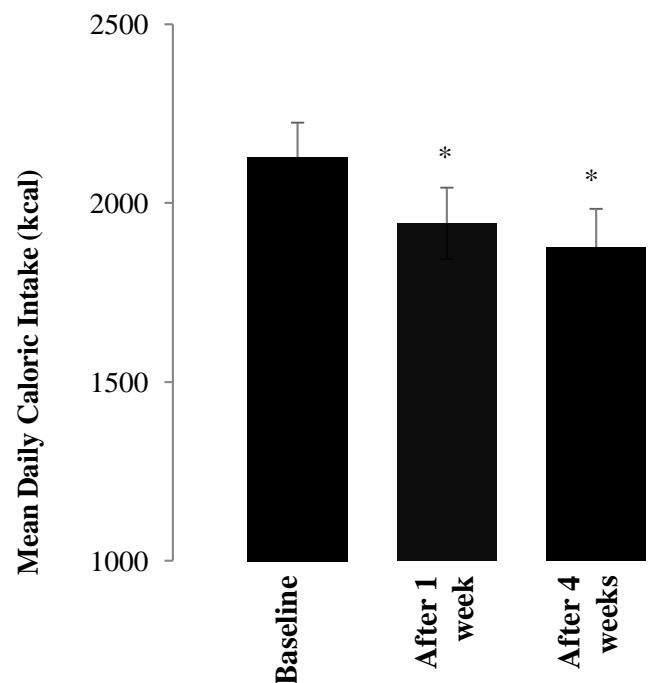


Figure 1. Mean daily caloric intake, measured as mean kcal, significantly reduced at week-1 and week-4 of treatment period after baseline. All values were expressed as mean \pm SEM; * $p < 0.01$ versus baseline.

kappa-carrageenan and xanthan gum. An *in vitro* study has shown that IQP-AK-102 swells approximately 333 times of its own weight (non-reported data). Therefore, it was estimated that two capsules of IQP-AK-102 per meal (i.e. 1290 mg) could fill approximately 29 to 43% of the stomach capacity of a normal adult based on Daniels and Allum (2006) reporting the normal physiological capacity of an adult's stomach in a range between 1000 and 1500 ml.

In this study, both the short-term (1 week) and long-term (4 weeks) administration of IQP-AK-102 were found to significantly improve satiety, reduce hunger and

decrease dietary energy intake in otherwise healthy overweight subjects who were allowed *ad libitum* calorie intake, leading to a statistically significant weight loss of 0.49 (SD 1.21) kg compared to baseline. The weight loss effect presented in the current study is in agreement with the efficacy shown in the previous study by Bongartz et al. (2016), where a *post-hoc* subgroup analysis of the overweight subjects ($n = 77$) found that IQP-AK-102 treated subjects lost significantly more body weight than the overweight placebo subjects [1.10 (SD 1.46) kg versus 0.31 (SD 1.11) kg, $p < 0.020$], at week-4, notably in conjunction with a reduced calorie diet. Similarly, a statistical significance was observed in the *post-hoc* analysis of overweight subjects for week-8 [IQP-AK-102: 2.00 (SD 1.63) kg versus placebo: 0.20 (SD 1.67) kg, $p < 0.001$] and week-12 [IQP-AK-102: 3.33 (SD 2.22) kg versus placebo: 0.12 (SD 1.77) kg, $p < 0.001$] respectively (unpublished data).

Taken into consideration the clinical evidence available for other soluble fibers and the findings of the current study, it can be concluded that IQP-AK-102 promotes weight-loss through the regulation of appetite. Nevertheless, it has to be noted that there are some limitations to the current study. Firstly, the study design was an open label study, thus both subjects and study investigators were aware of the treatment assigned to the subject. Secondly, although proper training was provided to all subjects on how to complete the subjects' diary prior to the study commencement, respective appetite and food intake measurements rely on self-reported data. These factors may introduce a study bias affecting interpretation of the observed study results. Therefore, a randomized, double-blind, placebo-controlled with stratification by BMI and energy intake study design to reduce intragroup variance in baseline characteristics could be of interest in the further course of research. Moreover, larger prospective studies may be of interest to confirm the current findings in other ethnic populations and under different dietary regimes. Last but not least, since soluble fibers were reported to delay nutrient absorption, especially of glucose, it may be warranted to investigate the effect of IQP-AK-102 on post-prandial glucose level and insulin response in future studies.

Conclusions

The results presented in this study confirm the weight loss effect of IQP-AK-102 reported in the trial by Bongartz et al. (2016). Additionally, the present study provided evidence that IQP-AK-102 facilitates weight loss through promotion of satiety and reduction of appetite. More importantly, IQP-AK-102 exerted significant effects in suppressing appetite in an *ad libitum* diet regime, and the effects were sustained after 4 weeks of continuous treatment. This is in line with EFSA's recommendation that sustained reduction of appetite needs to be shown to exclude adaptation effect (European Food Safety

Authority, 2012), and is relevant for successful body weight loss and weight maintenance. In addition, there was no report of side effect related to the use of IQP-AK-102, again consistent with the findings of trial by Bongartz et al. (2016). Nevertheless, further investigations on the long-term efficacy and safety of IQP-AK-102 in terms of weight loss, appetite reduction and maintenance of body weight may be warranted. In conclusion, IQP-AK-102 provides a comprehensive natural weight management approach that is both effective and safe.

Declaration of interest

This study was funded by InQpharm Europe Ltd. Pee-Win Chong and JooLian Khoo are employees of InQpharm Europe Ltd. The authors have indicated that they have no other conflicts of interest regarding the content of this article.

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