Comparable Clinical Outcomes between Glucosamine Sulfate-Potassium Chloride and Glucosamine Sulfate Sodium Chloride in Patients with Mild and Moderate Knee Osteoarthritis: A Randomized, Double-Blind Study

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Background: *Glucosamine sulfate has been recommended for treatment of knee osteoarthritis in several published guidelines. However, there are various preparations of glucosamine that may result in different pharmacokinetic and clinical outcomes.*
Objectives: *Comparison of clinical outcomes of two different preparations of glucosamine sulfate (Sodium chloride salt and Potassium chloride salt) in patients with mild and moderate degree knee osteoarthritis. Laboratory tests to monitor drug safety were also studied.*
Material and Method: *Patients with symptomatic mild and moderate degree knee osteoarthritis were randomly assigned to receive treatment with either glucosamine sulfate with potassium salt (GS-K) 1500 mg daily or glucosamine sulfate with sodium salt (GS-Na) 1500 mg daily. Types of treatments were blinded to both patients and evaluators. Clinical assessments were done two weeks prior to initiation of treatment and then every four weeks until the sixteen week of treatment. Standing knee radiographs were taken at the initial visit. Patients with Ahlback stage 1 to 4 were included in the current study. Clinical data included range of motion, presence or absence of joint effusion, WOMAC and SF 36. Laboratory studies were also done to evaluate drug safety, including BUN, creatinine, electrolytes, and liver function test. Adverse drug reactions were also recorded.*
Results: *Ninety patients with mild and moderate knee osteoarthritis (Ahlback grade 1-4) were randomized to two treatment groups, forty-five patients each. Demographic data and initial clinical assessment were similar in both groups. Both groups demonstrated improvement of WOMAC score and SF-36 at final follow-up but this did not reach statistical significance. Differences of WOMAC score and SF-36 between the two groups were not significant at any follow-up visit. Serum potassium level increased more significantly in the GS-K group but did not exceed normal value.*
Conclusion: *In this short-term randomized comparison, glucosamine sulfate with potassium salt (GS-K) is as effective in pain relief and as safe as glucosamine sulfate with sodium salt (GS-Na) for treatment of mild and moderate degree knee osteoarthritis.*

Keywords: *Ahlback, glucosamine sulfate, knee, osteoarthritis, SF-36, WOMAC*

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Several studies have demonstrated efficacy in the symptomatic treatment of glucosamine sulfate in knee osteoarthritis[1-4]. Currently, glucosamine sulfate is part of EULAR and AORSI recommendations for treatment of knee osteoarthritis. However, there are various preparations of glucosamine, which may result in different pharmacokinetic and clinical outcomes[5,6]. Due to the unstable nature of crystalline glucosamine sulfate, a stabilizing agent such as sodium or potassium chloride must be added during manufacturing process[5]. In the present study the authors conducted clinical comparison, both therapeutic efficacy and safety, between the novel potassium chloride stabilized crystalline glucosamine sulfate powder and the original sodium chloride stabilized crystalline glucosamine sulfate powder.

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Material and Method

Patients with unilateral mild and moderate knee osteoarthritis at King Chulalongkorn Memorial Hospital (KCMH) orthopedic clinic were asked to participate in

the present clinical study. Radiographs were taken at initial visit to confirm knee osteoarthritis and then graded according to Ahlback classification. One-hundred patients with Ahlback grade 1 to 4 were recruited into the present study. Details of inclusion, exclusion and withdrawal criteria are shown in Table 1. Patients were randomized to receive a packet of either 1500 mg glucosamine sulfate stabilized with potassium chloride (GS-K) [Flexsa, Mega Lifesciences, Bangkok, Thailand] or 1500 mg glucosamine sulfate stabilized with sodium chloride (GS-Na) [Viartril-S, Rottapharm] daily, before meals, for 16 weeks. Only acetaminophen was allowed for pain relief. Patients were scheduled for follow-up visit every 4 weeks after initiation of treatment. Exact amount of glucosamine packets were given to the patient for each follow-up appointment. Patients were instructed to return all packets of glucosamine, either used or unused, at the following visit for record. Amount of acetaminophen used was also recorded at each visit.

Clinical evaluations were done two weeks before initiation of treatment (visit 0), at initiation of treatment (visit 1), and then every four weeks until complete at 16 weeks (visit 5). Physical examinations of the affected knee included range of motion, coronal plane alignment, flexion contracture, and presence or absence of effusion. Blood samples were taken for laboratory tests at patient screening (visit 0), at two months (visit 3), and at the end of the trial (visit 5). These tests include serum level of BUN, Creatinine, electrolyte, phosphate, SGOT, SGPT, and ESR. WOMAC score and SF-36 were also recorded at visit 0, 3, and 5. Patients were asked to rate their global satisfaction of the treatment at the final visit. All adverse events were recorded and changes in laboratory blood test were evaluated for the safety and tolerability assessments of the study drugs.

The sample size was calculated from:

$$N_0 = \frac{\left\{ Z_\alpha \left[\bar{P}\,\bar{Q} \frac{(\lambda + 1)}{\lambda} \right]^{\square} + Z_\beta \left[P_0 Q_0 + \frac{P_1 Q_1}{\lambda} \right]^{\square} \right\}^2}{(P_1 - P_0)^2}$$

$P_0 = 0.1$, $P_1 = 0.5$, $Q_0 = 0.9$, $Q_1 = 0.5$, $\bar{P} = 0.3$, $\bar{Q} = 0.7$, $\lambda = 1$
$\alpha = 0.01$, $\beta = 90\%$, $Z_\alpha = 2.576$, $Z_\beta = 1.282$

$$N_0 = \frac{\left\{ 2.576 \left[0.3 \text{x} 0.7 \text{x} \frac{(1+1)}{1} \right]^{\square} + 1.282 \left[0.1 \text{x} 0.9 + \frac{0.5 \text{x} 0.5}{1} \right]^{\square} \right\}^2}{(0.5 - 0.1)^2}$$

$= 36.5$

The authors considered to recruit 50 cases in each group.

Statistical analysis was done with paired t-test for intra-group analysis and independent t-test and Mann-Whitney U-test for inter-group analysis. A p-value of < 0.05 was used to determined statistical significance. SPSS (version 16) was used for statistical analysis.

Results

One hundred patients were initially recruited in to the present study. Ten patients dropouts, five in each group, resulting in 45 patients for analysis in each group. Three drop-outs were due to adverse drug event (1 in GS-K group and 2 in GS-Na group). Two drop-outs were due to lack of improvement (1 in each group). Five other patients did not complete the scheduled visits due to other reasons (Fig. 1).

There were two males in GS-K group and six males in GS-Na group, which were not statistically different. The GS-K group had a mean age of 56.40 ± 8.8 years, mean body weight of 60.96 ± 8.2 kg and mean BMI of 25.37 ± 3.4 kg/m^2. The GS-Na group had a mean age of 60.09 ± 8.4 years, mean body weight of $60.68 \pm$

Table 1. Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Male and female age 35-80 years	Age < 35 or > 80 years
BMI $\leq$ 30kg/m^2	BMI > 30 kg/m^2
Mild to moderate knee osteoarthritis (Ahlback gr 1-4)	Severe knee osteoarthritis (Ahlback gr 5,6)
No concurrent treatment for osteoarthritis or has been stop for at least 2 weeks prior to initiation of trial	Currently using NSAIDS and/or corticosteroids for any other conditions
	Previous knee surgery
	Impaired liver and/or kidney functions
	History of allergy to glucosamine and/or acetaminophen

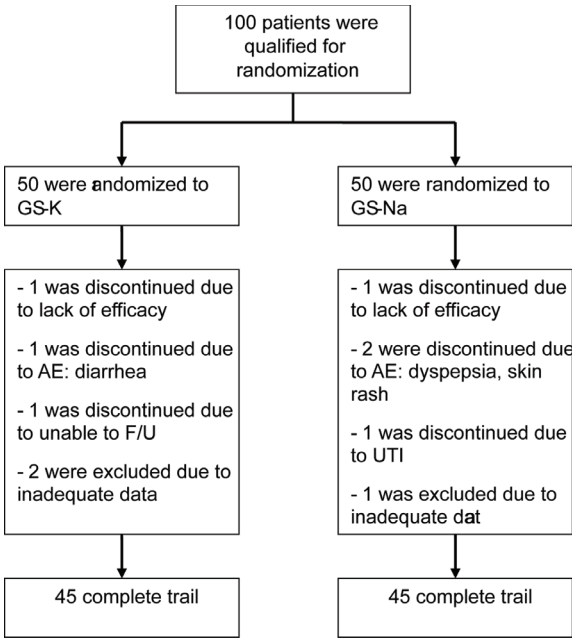

Fig. 1 Patients with knee osteoarthritis enrolled in 16-week clinical trail of GS-K vs. GS-Na

Table 2. Baseline characteristics for patients enrolled in clinical study of GS-K and GS-Na for treatment of knee OA

	GS-K	GS-Na	p-value*
	Mean (SD)	Mean (SD)	
Female	43 (95.6)	39 (86.7)	
Male	2 (4.4)	6 (13.3)	0.141
Age	56.4 (8.8)	60.09 (8.4)	0.056
Weight	60.96 (8.2)	60.68 (8.9)	0.853
Height	155.18 (4.3)	156.34 (6.7)	0.515
BMI	25.37 (3.4)	24.82 (3.7)	0.506
Right knee	25 (55.6)	29 (64.4)	
Left knee	20 (44.4)	16 (35.6)	0.392
Swelling			
Yes	6 (13.3)	6 (13.3)	1.000
No	39 (86.7)	39 (86.7)	
Ahlback			
Grade 1	19 (42.2)	21 (46.7)	
Grade 2	20 (44.4)	14 (31.1)	
Grade 3	4 (8.9)	7 (15.6)	
Grade 4	2 (4.4)	3 (6.7)	0.917

* Mann-Whitney U test

8.9 kg and mean BMI of 24.82 $\pm$ 3.7 kg/m^2. None of these data were significantly different. The radiographs were classified according to Ahlback classification. The GS-K group composed of 19 grade I, 20 grade II, four grade III, and two grade IV while the GS-Na group composed of 21 grade I, 14 grade II, seven grade III, and three grade IV. These differences are not statistically significant (Table 2).

Clinical outcomes

WOMAC total score and subscale scores were not different between the two groups at the screening visit. Total score and subscale scores in both groups decreased after 2 and 4 months of treatment. However, the decreased score did not reach statistical significant, nor did they significantly differed between the two groups (Table 3).

SF-36 followed the same trends as WOMAC score by demonstrated non-significant differences between two groups at initial and two subsequent visits. The final score in both groups also decrease insignificantly from the beginning of the study (Table 4).

The authors also obtained subjective opinions from 37 GS-K and 38 GS-Na patients. They were asked to rate the outcomes as excellent, good, fair, or poor. In contrast to WOMAC and SF-36 scores, majority of the patients rated their outcomes as good or excellent. None rated their outcomes as poor.

Laboratory results

Serum level of BUN, Creatinine, SGOT and SGPT did not change significantly during the present study period in both groups and did not differ between each group at any visit. Serum sodium did not change significantly throughout the present study in both groups. There were also no differences between the two groups at each visit. Serum potassium increased significantly in GS-K group between visit 0 and visit 3 ($p = 0.012$) but did not exceed normal range value (3.5-5.5 mmol/L) (Fig. 2). However, the potassium level then decreased at visit 5 and did not differ significantly from visit 0 (Table 5). The GS-K group also demonstrated higher serum potassium level than GS-Na group at visit 3 and visit 5 ($p = 0.007$ and 0.046, respectively).

Discussion

Currently, glucosamine is widely use as a pharmacological agent or nutritional supplement for symptomatic treatment of knee osteoarthritis.

Table 3. The WOMAC score of GS-K and GS-Na groups during the 16-week treatment period

WOMAC score	Visit 0 Mean (SD)	Visit 3 Mean (SD)	Visit 5 Mean (SD)	p-value* visit 0-visit 5
Pain subscale				
GS-K	19.22 (11.99)	15.89 (10.83)	15.98 (11.46)	0.070
GS-Na	17.24 (11.11)	16.78 (10.31)	15 (10.5)	0.097
p-value**	0.419	0.691	0.674	
Stiffness subscale				
GS-K	7.62 (5.67)	6.31 (5.37)	6.24 (4.72)	0.097
GS-Na	7.69 (5.21)	6.53 (5.07)	6.29 (4.65)	0.047
p-value**	0.954	0.840	0.964	
Function subscale				
GS-K	50.47 (31.07)	46 (28.69)	48.53 (31.98)	0.698
GS-Na	54.51 (26.44)	54.42 (29.85)	48.47 (27.89)	0.161
p-value**	0.508	0.176	0.992	
Total WOMAC score				
GS-K	77.31 (44.25)	68.2 (43.1)	70.76 (43.84)	0.314
GS-Na	79.44 (37.77)	77.73 (42.39)	69.76 (40.5)	0.080
p-value**	0.806	0.293	0.911	

* Pair t-test, ** 2 independent t-test

Table 4. The SF-36 of GS-K and GS-Na groups during the 16-week treatment period

SF-36	Visit 0 Mean (SD)	Visit 3 Mean (SD)	Visit 5 Mean (SD)	p-value* visit 0-visit 5
GS-K	86.04 (19.49)	83.09 (16.48)	83.33 (13.67)	0.346
GS-Na	83.49 (12.19)	81.16 (15.29)	82.89 (13.88)	0.772
p-value**	0.458	0.566	0.879	

* Pair t-test, ** 2 independent t-test

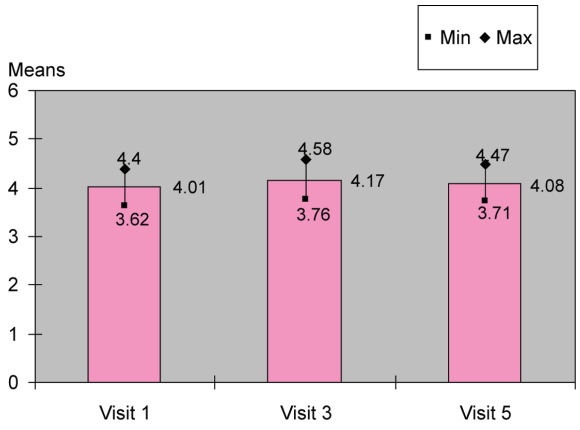

Fig. 2 The potassium level of the patient in GS-K group increases in visit 3 but not exceed the normal range of potassium level in any visit

Several studies reported that different preparations of glucosamine might not have equivalent clinical outcomes[5,6]. Nonetheless, glucosamine sulfate is being recommended for the treatment of knee and hip osteoarthritis in many published guidelines[7-11]. EULAR (European League Against Rheumatism) and OARSI (OsteoArthritis Research Society International) recommended glucosamine sulfate as effective and safe treatment for knee osteoarthritis with highest level of evidence and strength of recommendation[9-11]. On the other hand, the effectiveness of glucosamine hydrochloride has been questioned by the AAOS.

In 2005, in a meta-analysis of glucosamine for treatment of osteoarthritis as reported by the Cochrane collaboration showed that only Rottapharm's preparation of crystalline glucosamine sulfate demonstrated superior efficacy to placebo in the

Table 5. The laboratory blood test of the patients in both groups during the treatment period

	Visit			p-value* (V0-V3)	p-value* (V0-V5)	p-value* (V3-V5)
	Visit 0 Mean (SD)	Visit 3 Mean (SD)	Visit 5 Mean (SD)			
BUN						
GS-K	12.96 (3.69)	13.69 (4.08)	13.04 (4.44)	0.090	0.840	0.200
GS-Na	12.44 (3.17)	13.02 (3.81)	12.89 (4.21)	0.290	0.470	0.818
p-value**	0.483	0.425	0.865			
Creatinine						
GS-K	0.679 (0.11)	0.651 (0.11)	0.675 (0.15)	0.039	0.805	0.113
GS-Na	0.724 (0.28)	0.714 (0.24)	0.729 (0.24)	0.612	0.683	0.250
p-value**	0.316	0.113	0.202			
Phosphate						
GS-K	3.42 (0.49)	3.54 (0.52)	3.49 (0.46)	0.190	0.244	0.464
GS-Na	3.4 (0.49)	3.43 (0.49)	3.36 (0.37)	0.648	0.441	0.230
p-value**	0.915	0.331	0.150			
SGOT						
GS-K	23.22 (9.77)	26.24 (12.56)	24.64 (11.35)	0.036	0.207	0.173
GS-Na	24.29 (9.11)	22.78 (8)	23.78 (8.13)	0.071	0.660	0.376
p-value**	0.594	0.122	0.678			
SGPT						
GS-K	22.64 (10.33)	22.82 (11.62)	23.31 (13.86)	0.893	0.672	0.744
GS-Na	24.58 (13.66)	21.62 (11.68)	22.64 (13.15)	0.005	0.163	0.447
p-value**	0.451	0.626	0.815			
Sodium (Na)						
GS-K	140.24 (2.57)	139.6 (2.53)	139.44 (2.38)	0.157	0.115	0.739
GS-Na	140.07 (2.36)	140.02 (2.58)	139.78 (2.32)	0.922	0.553	0.644
p-value**	0.733	0.435	0.502			
Potassium (K)						
GS-K	4.01 (0.4)	4.17 (0.42)	4.08 (0.39)	0.012	0.320	0.167
GS-Na	4.02 (0.37)	3.93 (0.39)	3.92 (0.37)	0.141	0.062	0.814
p-value**	0.870	0.007	0.046			
Chloride						
GS-K	100.24 (2.81)	101.2 (3.05)	103.47 (2.35)	0.090	0.000	0.000
GS-Na	100.2 (2.74)	102.78 (3.38)	103.44 (3.29)	0.000	0.000	0.199
p-value**	0.940	0.022	0.971			
Carbon-dioxide						
GS-K	27.6 (2.26)	27.38 (2.49)	26.76 (2.22)	0.578	0.026	0.064
GS-Na	28.56 (2.3)	27.67 (2.39)	27.6 (2.15)	0.014	0.007	0.863
p-value**	0.050	0.576	0.070			

* Pair t-test, ** 2 independent t-test

treatment of pain and functional impairment from symptomatic osteoarthritis[12]. The present study demonstrated that glucosamine sulfate stabilized with potassium chloride [Flexsa, Mega Lifesciences, Bangkok, Thailand] had equivalent clinical outcomes when compared to the original glucosamine sulfate stabilized with sodium chloride [Viartril-S, Rottapharm]. In the current study, WOMAC total score and subscale scores and SF-36 in both groups decreased similarly after 2 and 4 months of treatment, although the decreased score did not reach statistical significant in both groups. These findings are compatible with many previous glucosamine versus placebo RCT studies, where significant pain and functional improvement can be demonstrated with Lequesne index but not with WOMAC or SF-36[12].

In contrast to WOMAC and SF-36 outcomes, most of our patients rated their satisfaction as good and excellent at the final visit. It is also noteworthy that the amount of paracetamol consumed decreased significantly from visit 1 to visit 5 in GS-K group (0.000) but not in GS-Na group ($p = 0.059$).

The present study demonstrated that GS-K is as safe as GS-Na and as previously reported[3,13-16]. Three adverse events were reported. The GS-K group had one case of diarrhea while the GS-Na group had one case of dyspepsia and one case of skin rash. All symptoms were mild and spontaneously subsided after glucosamine was discontinued.

The serum level of BUN, Creatinine, SGOP, SGPT, and sodium were monitored during the treatment period, did not change significantly in both groups and did not differ between each group at any visit. Serum potassium level increased significantly between visits 0 and 3 ($p = 0.012$) in the GS-K group but did not exceed the normal ranges. It then decreased at visit 5. This finding may be a transient rising of serum potassium without clinical significant, since the fact that a 1500 mg packet of glucosamine sulfate stabilized with potassium chloride contains only 255 mg potassium approximately 7.2% of the daily recommendation. Even though there was no adverse event related to the potassium level in this study, we would recommend a close monitoring in patients with impaired renal function.

A weakness of this study includes the relatively short follow-up period. The authors do not consider the lack of a placebo group as a pitfall, since the objective of this study was to compare the efficacy of a newer preparation of glucosamine sulfate with the original one the efficacy of which has been proven and included as a recommendation for treatment of osteoarthritis[1-4,9-11].

Conclusion

In the present study, the short-term clinical outcomes of patients with mild to moderate knee osteoarthritis treated with either 1500 gram of glucosamine sulfate stabilized with potassium chloride (GS-K) or 1500 gram of glucosamine sulfate stabilized with sodium chloride (GS-Na) were similar. Serum potassium levels increased in patients treated with glucosamine sulfate stabilized with potassium chloride (GS-K) group but did not exceed normal values.

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การศึกษาเปรียบเทียบผลการรักษาผู้ป่วยโรคข้อเข่าเสื่อมระดับน้อยและปานกลางด้วยยากลูโคซามีนซัลเฟตเกลือโปแตสเซียมคลอไรด์ กับยากลูโคซามีนซัลเฟตเกลือโซเดียมคลอไรด์: แบบสุ่มและปกปิดสองทาง

ยงศักดิ์ หวังรุ่งทรัพย์, อารี ตนาวลี, วัชระ วิไลรัตน์, สีหธัช งามอุโฆษ

ภูมิหลัง: *กลูโคซามีนซัลเฟตได้รับการยอมรับเป็นยาที่ใช้ในการรักษาโรคข้อเข่าเสื่อม แต่เนื่องจากยานี้มีส่วนประกอบและการผลิตที่แตกต่างกัน อาจทำให้ผลการรักษามีความแตกต่างกัน*

วัตถุประสงค์: *เปรียบเทียบผลการรักษาข้อเข่าเสื่อมด้วยยากลูโคซามีนซัลเฟตเกลือโปแตสเซียมคลอไรด์ กับยากลูโคซามีนซัลเฟตเกลือโซเดียมคลอไรด์ รวมทั้งติดตามความปลอดภัยในการใช้ยาทั้งสองชนิด*

วัสดุและวิธีการ: *ผู้ป่วยที่มีอาการข้อเข่าเสื่อมระดับน้อยและปานกลางที่ผ่านการคัดกรองจำนวน 100 ราย ถูกสุ่มเพื่อรับยากลูโคซามีนซัลเฟตเกลือโปแตสเซียมคลอไรด์วันละ 1,500 มิลลิกรัม หรือ ยากลูโคซามีนซัลเฟตเกลือโซเดียมคลอไรด์วันละ 1,500 มิลลิกรัม รายละ 16 สัปดาห์ ผู้ป่วยจะได้รับการนัดตรวจและรับยาทุก 4 สัปดาห์ รวมทั้งวันสุดท้ายของการรักษารวม 5 ครั้ง ทั้งผู้ป่วยและผู้ประเมินผลการรักษาจะถูกปกปิดชนิดของยาที่ใช้ การเปรียบเทียบประสิทธิภาพของยาทั้งสองกลุ่มจากคะแนน WOMAC, SF-36 รวมทั้งการให้ผู้ป่วยประเมินความพึงพอใจของการรักษาในการตรวจครั้งสุดท้ายด้วย การเปรียบเทียบความปลอดภัยของยาทั้งสองกลุ่มจากการตรวจเลือดติดตามระดับของ BUN, Cr, electrolyte, SGOT, SGPT และ ESR รวมทั้งการติดตามอาการข้างเคียงจากการใช้ยาทั้งสองกลุ่ม*

ผลการศึกษา: *ยาทั้งสองชนิดมีประสิทธิภาพในการรักษาผู้ป่วยข้อเข่าเสื่อมได้ โดยคะแนน WOMAC, SF-36 ดีขึ้นจากการติดตามผลการรักษาครั้งที่ 3 และ 5 แต่ไม่มีความแตกต่างอย่างมีนัยสำคัญทางสถิติ จากการตรวจเลือดพบว่าระดับของโปแตสเซียมสูงขึ้นในกลุ่มที่ใช้ยากลูโคซามีนซัลเฟตเกลือโปแตสเซียมคลอไรด์ แต่ไม่เกินค่าปกติ อาการข้างเคียงของการรักษาไม่แตกต่างกันในสองกลุ่ม*

สรุป: *จากการศึกษาพบว่ายาทั้งสองกลุ่มมีประสิทธิภาพในการรักษาโรคข้อเข่าเสื่อม และมีความปลอดภัยในการรักษาไม่แตกต่างกัน*