印尼复方穿心莲发酵蜂蜜汤剂“JAMSI”对高血糖患者的即刻降糖功效临床验证

Ning Harmanto[1], Prapti Utami[2], Willie Japaries(叶伟生)[3]

(1 印尼 PT Mahkotadewa Indonesia 有限公司; 2 印尼 CV Sekar Utami Toga 个体公司;
3 印尼中医师资格核准机构(LSK Sinshe),印尼纳兰陀佛教中医学院(STAB Nalanda))

摘要 目的:研究印尼复方穿心莲发酵蜂蜜汤剂”JAMSI”(由印尼 PT Mahkotadewa Indonesia 公司生产;印尼食品药品管理局注册号:TR053649111)对高血糖患者的即刻降糖功效。方法:本研究设计为对高血糖患者治疗前对治疗后的降糖功效评价,研究患者来自参观本产品展览台的来宾,他们必须患有高血糖或糖尿病并愿意参与本研究。检测临时毛细血管血血糖使用德国制造的 Accu – Chek Active 血糖检测仪在服用 JAMSI 汤剂前及服用后 1 h。所获得的配对血糖数据按统计学一边 t 检验法分析并总结,统计学意义界限 $\alpha = 0.05$。结果:在两次展览中即 2013 年 2 月 16—23 日在雅加达,获得 34 位合格患者为本研究患者,性别上分为 20 女和 14 男,其中 20 位正在服用降血糖西药。患者年龄最小 22 岁,最老 74 岁,平均(52.26 ± 10.10)岁,糖尿史由 1 ~ 33 年,平均(9.36 ± 8.27)年。患者的平均毛血管血血糖浓度在服用 JAMSI 汤剂前是(243.03 ± 97.97)mg/dL,而服用后 1 h 是(197.94 ± 100.01)mg/dL,两者差异有统计学意义($P < 0.01$)。按服用前血糖浓度高于 200 mg/dL 的患者对比服用前血糖浓度低于 200 mg/dL 的患者分析结果显示服用 JAMSI 后降低血糖幅度在前者比后者更明显(表 3)。而在正在服用降血糖西药者与没有服用降血糖药者之间降血糖幅度差异无统计学意义($P > 0.05$)。结论:受检验的印尼复方穿心莲发酵蜂蜜汤剂“JAMSI”显示非常显著的即刻降血糖功效;此外在被研究的患者中没有发现任何严重不良反应。有关该药剂的中长期效果有待继续研究证明。

关键词 糖尿病;降血糖;穿心莲;发酵蜂蜜

Clinical Observation on The Immediate Hypoglycemic Effect of Andrographis-Fermented Honey Formula Herbal Oral Solution “Jamsi” on Hyperglycemic Volunteers

Ning Harmanto[1], Prapti Utami[2], Willie Japaries[3]

(1 *PT Mahkotadewa Indonesia*; 2 *CV Sekar Utami Toga*; 3 *Sinshe Competence Certification Board* (*LSK Sinshe*))

Abstract **Objective**: To study the immediate hypoglycemic effect of Andrographis-fermented honey oral solution formula “JAMSI” (produced by PT Mahkotadewa Indonesia; registered at Indonesian Food and Drugs Authority: TR053649111) among 34 hyperglycemic volunteers. **Methods**: This study was designed as a pre and post treatment's effect evaluation among hyperglycemic volunteers. Volunteers were recruited from visitors to the “JAMSI” boothe during the study, who were hyperglycemic and ready to be tested with the “Jamsi” remedy under study. Their blood sugar were tested using glucometer Accu-Chek Active (made in Germany) before and one hour after consuming the “JAMSI” oral solution. The paired blood sugar data were analyzed using student-t test with paired samples, one sided, with significance cut off point $\alpha = 0.05$. **Results**: During two study days on 16th and 23rd February 2013 in Jakarta, there were 34 volunteers eligible to the study. They consisted of 20 female and 14 male, among which 20 volunteers were still consuming western hypoglycemic medicine. Their age ranged from 22 to 74 years (52.26 ± 10.10 years), with diabetes mellitus history ranging from 1 to 33 years (9.36 ± 8.27 years). Their average capillary blood sugar level before consumption of the tested “jamu” remedy was (243.03 ± 97.97) mg/dl and one hour after consumption of the remedy was (197.94 ± 100.01) mg/dl. The difference was highly significant ($P < 0.01$). Analysis upon those with initial blood sugar above 200 mg/dl versus those with lower than 200 mg/dl indicated that the reduction of blood sugar level was more prominent among those with higher initial blood sugar level (table-3). The hypoglycemic effect was not significantly differently ($P > 0.05$) between those still consuming oral antidiabetic drugs and those not consuming oral antidiabetic drugs. **Conclusion**: The “JAMSI” remedy under study showed very significant immediate hypoglycemic effect and apparently free from serious utoward effects among the tested volunteers. More studies are required to assess the medium and long term effects of the “JAMSI” remedy.

Key Words Diabetes mellitus; Hyperglycemia; Andrographis; Fermented honey

中图分类号:R289;R255.4 **文献标识码**:A **doi**:10.3969/j.issn.1673 – 7202.2014.02.034

糖尿病是当前的世界公共卫生难题。其发病率持续上升,尤其是在发展中国家[1-2]。为克服该难题我们应动用全部有效方法,包括传统药剂。按印尼国家统计数据,传统药物的使用率稳步上升[3]。许多印尼

的本土“赞木”草药被公认对糖尿病病人有治疗作用。一部分也通过体外或体内试验被证实有效,如穿心莲(Andrographis paniculata),仙人冠果皮(Phaleria macrocarpa),和巴戟果(Morinda citrifolia)[4-5]。该三种草药提取物加上发酵蜂蜜[6-7],棕榈糖[8-9],组合成有特效的赞木复方穿心莲发酵蜂蜜汤剂叫“JAMSI”(在印尼食品药品管理局注册号:TR053649111)。本研究旨在初步探索该药剂在高血糖患者,即糖尿病患者或未确诊为糖尿病患者(诊断标准按印尼内分泌专科协会PERKENI,2011 年发布的标准[10])的即刻降血糖功效。

1 资料与方法

1.1 一般资料 本研究主要观察患者服用“JAMSI”前及服用后 1 h 临时毛细血管血糖浓度的变化。“JAMSI”汤剂由印尼 PT Mahkotadewa Indonesia 公司生产,成分为氧化水 70 mL,蜂蜜 20 mL,棕榈糖 10 g,Phaleria macrocarpa 提取物 120 mg,Andrographis paniculata 提取物 120 mg,Morinda citrifolia 提取物 64 mg。患者总共 34 人,20 女和 14 男。

1.2 纳入标准 研究患者来自参观“JAMSI”两次展览(2013 年 2 月 16—23 日)柜台并符合如下纳入标准的患者:1)成年人(20 岁以上);2)临时毛细血管血糖浓度 200 mg/dL 或以上者诊断为糖尿病,而浓度在 90~199 mg/dL 之间的为未确定是糖尿病;3)愿意遵守研究方案,即服用两汤匙“JAMSI”汤剂前及服用后 1 h 检测其临时毛细血管血血糖浓度。

表 1 各个 34 位患者的总体特征及服用”JAMSI”汤剂之前及服用后 1 h 的血糖浓度

编号	性别	姓名记号	年龄	糖尿病史	所使用西药	服用 Jamsi 时间	服用前血糖浓度	服用后 1 h 血糖浓度
1	M	Aap	22		无	10.15	114	116
2	M	Bah	38		无	10.00	180	101
3	M	Riy	39		无	12.10	146	112
4	F	EN	41	自 2008	Glucovance 500/2,5 Mg Jeli gamat	10.40	343	374
5	F	At	43			11.15	388	374
6	F	Id	43	1 年前	Glukopag1/2tablet		153	113
7	F	Ukp	43		无	10.30	127	109
8	M	Gan	47	自 2003	其他草药	14.30	202	126
9	F	LI	47		Metformil 500 Januvia 100	11.13	275	232
10	F	Ten	47	自 2004	Glucodex 80 Mg, Metformin 500 Mg	10.35	160	180
11	F	DI	47	自 2011	Amaril,一半	12.02	211	133
12	F	SPS	48		无	10.35	329	273
13	F	ES	50	自 1997	Insulin novoropid etc	10.19	284	237
14	F	Mak	50		无		182	99
15	M	DU	52	不知	无	10.18	216	134
16	M	Sup	52	自 2010	医生处方	10.15	228	189
17	F	Yos	52	10 年前	Amaril 500, Januvia	10.15	181	120
18	M	TK	53	自 2010		12.10	262	220
19	M	SW	53	自 2013	None	12.25	491	435
20	F	Ren	53	自 1997	Medformin, Andrographis	18.00	292	244
21	F	MWS	56	自 2013	其他草药	14.30	214	136
22	F	RL	57			14.33	230	218
23	F	CS	57	自 2012	Metformin, glibenclamide	09.50	336	152
24	F	JbA	58	2008	Glucovance, Mahkotadewa	09.57	182	127
25	M	MS	59	自 2006	Glukopag	9.50	341	318
26	M	HHK	59	自 1990	Daonil/Diabetmin	09.50	397	359
27	F	FT	59	自 2009	Meoformin	10.05	308	272
28	F	EP	59	自 2005	Diamicron, Glucopag, 草药	10.31	337	288
29	M	HS	60	自 1993	Insulin, lasix	10.30	179	98
30	F	Sur	60	自 2009	Glucopag, 其他草药	15.30	182	149
31	M	AS	62	12 年	Gluvas		113	68
32	M	Anh	63	自 2012		07.00	117	111
33	M	Rah	74	自 1979	Metformin, glibenclamide, Glucopag	15.30	420	365
34	F	KS	74	自 1991	Glucopag SR, Jenovia, Insulin inj	11.00	143	148

1.3 方法 患者接受研究方案之解释后决定愿意遵守就在同意书上签字,然后其服用“JAMSI”前及服用后 1 h 临后的毛细血管血血糖浓度被检测并记录下来待统计学处理。患者服用两汤匙“JAMSI”前及服用后

1 h 临时的毛细血管血血糖浓度的变化按统计学配对一边 t 检验法处理而有效差异限度 α 为 0.05。检测血糖浓度使用德国制的 Accu－Chek Active 血糖检测器。

2　结果

患者年龄 22～74 岁，平均（52.26±10.10）岁，糖尿病史平均（9.36±8.27）年，大部分（21/34）还在使用降血糖西药（见表 1）。服用"JAMSI"汤剂之前的平均血糖浓度是（243.03±97.97）mg/dL 而服用后 1 h 是（197.94±100.01）mg/dL，一边配对 t 检验法，得出 $P=(3.8877\times10^{-8})<0.05$，两者的差异有统计学意义（$P<0.01$）。没有发现突出的不良反应，只有 2 位患者主诉短暂的头晕活动后即消失。如果把临时血糖 200 mg/dL 或以上的与 200 mg/dL 以下的患者对比分析，如表 2 显示服用"JAMSI"汤剂后血糖降低幅度在前者比后者更明显。然而如果把正在使用降血糖西药的（n=21）与没有使用降血糖西药的（n=13）患者对比，显然两组的服用"JAMSI"汤剂后的血糖浓度都显著下降（表 3）；而两组之间的服用"JAMSI"药剂之前及服用后 1 h 临时血糖浓度都无显著差异。图 1 显示 34 位患者服用"JAMSI"汤剂之前及服用后 1 h 的血糖浓度线图。

表 2　按服用"JAMSI"前的临时血糖浓度分组对比两组之间服用"JAMSI"之前及 1 h 之后的血糖浓度

分组	临时血糖浓度 <200 mg/dL	临时血糖浓度≥200 mg/dL
例数	14	20
服用汤剂前	154.21±27.71 mg/dL	305.2±79.15 mg/dL
服用汤剂后	117.93±27.71 mg/dL	253.95±94.07 mg/dL
P	0.000 69	0.000 01

注：一边配对 t 检验法，差异有统计学意义（$P<0.01$）。

表 3　按患者是否使用降血糖西药分组比较服用"JAMSI"汤剂之前及服用后 1 h 的血糖浓度变化

分组	未使用降血糖西药	使用降血糖西药
例数	13	21
服用汤剂前	229.54±113.13 mg/dL**	251.38±89.26 mg/dL**
服药汤剂后	186.77±111.85 mg/dL**	204.86±94.16 mg/dL**
P	0.000 174*	0.000 035 4*

注：*两组服用"JAMSI"汤剂之前及服用后 1 h 的血糖浓度变化明显（$P<0.001$），一边配对 t 检验法。**两组之间的服用"JAMSI"汤剂之前及服用后 1 h 的血糖浓度差异无统计学意义（$P>0.05$），一边配对 t 检验法。

3　讨论

基于以上对 34 患者的初步结果分析，显然"JAMSI"复方穿心莲发酵蜂蜜汤剂拥有非常显著的短期降血糖功效。其降血糖功效在起初较高的血糖浓度者尤其突出（见表 2）。无一患者发生低血糖或其他严重不良反应，提示"Jamsi"汤剂安全性高。但是有 3 位患者血糖稍微升高（其中一位增加"Jamsi"汤剂剂量后血糖有所降低），还有 2 位患者主诉短暂头晕。这可能提示有些患者对该药剂比较不敏感或需要增加剂量。

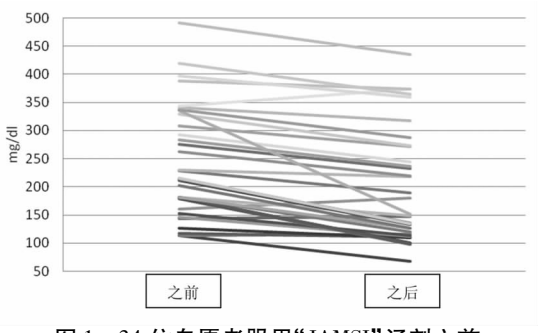

图 1　34 位自愿者服用"JAMSI"汤剂之前及服用后 1 h 的血糖浓度线图

表 3 显示本药剂降血糖效果在使用降血糖西药者与不使用降血糖西药者之间无明显差异。这可提示该"Jamsi"汤剂可以安全地跟降血糖西药同时服用。"Jamsi"汤剂的降血糖功效可能来自其五味成分，棕榈糖[8-9]，Phaleria macrocarpa 提取物，Andrographis paniculata 提取物，Morinda citrifolia 提取物[4-5,8]，及发酵蜂蜜[6-7,11]，各自皆曾经被发现拥有降血糖效果。有关该药剂对糖尿病患者的中长期疗效，包刮对糖尿病并发症的防治如何尚待继续研究。

本研究提示印尼复方穿心莲发酵蜂蜜汤剂"Jamsi"对高血糖患者拥有非常显著的短期降血糖作用（$P<0.01$）。使用降血糖西药看来对"Jamsi"汤剂的降血糖功效没有明显影响。此外也未发现任何严重不良反应。

笔者感谢 Inggrid Tania 医生和 Ernie P 教授对本报告初稿的指点及补充。

参考文献

[1] Soegondo S. Diagnosis dan klasifikasi diabetes melitus terkini. In: Soegondo S, Soewondo P, Subekti I (editors). Penatalaksanaan diabetes melitus terpadu. Jakarta: Balai Penerbit Fakultas Kedokteran Universitas Indonesia, 2009, pp: 19－29.

[2] Suyono S. Kecenderungan peningkatan jumlah penyandang diabetes. In: Soegondo S, Soewondo P, Subekti I (editors): Penatalaksanaan diabetes melitus terpadu. Jakarta: Balai Penerbit Fakultas Kedokteran Universitas Indonesia, 2009, pp: 3－10.

[3] Syarif A. Peranan toksikologi dalam pengembangan dan pemanfaatan obat bahan alam di Indonesia. Pidato pengukuhan guru besar tetap FKUI. Jakarta, 23 Feb. 2008.

[4] Untung O (editor in chief). Herbal Indonesia berkhasiat. Bukti ilmiah dan cara racik. Trubus Info Kit Vol. 8. Depok, no publication year, pp: 125－130, 148－153, 374－380.

[5] Winarto A, Adnyane IKM. Insitu study of repopulation beta cell pancreas of diabetic model rat after treating sambiloto. In: Prosiding "Globalization of Jamu Brand Indonesia. The 2nd international symposium on temula-

wak. The 40th meeting of national working group on Indonesian medicinal plant". IPB International Convention Center, Bogor, 2011, p: 164.

[6] Namdeo KP, Shekhar V. Chemical investigation of honey: a multiactive component of herbal therapeutic agent[J]. IJRAP, 2010, 1(1): 85 - 89.

[7] Syariffauzi. Mead sebagai minuman hasil fermentasi madu yang dapat mengobati berbagai penyakit, 2009. http://syariffauzi. wordpress. com/category/my - articles/page/3/

[8] Dharma AP. Indonesian medicinal plants[J]. Jakarta: Balai Pustaka, 1987, pp: 25 - 26, 37 - 38, 181 - 182.

[9] No name, no year. The usefulness of palm sugar for diabetes. http://obatdiabetesmelitus. net/makanan - manis/manfaat - gula - aren - untuk - diabetes.

[10] Perkumpulan Endokrinologi Indonesia (PERKENI). Konsensus pengelolaan dan pencegahan diabetes melitus tipe 2 di Indonesia. Cetakan keempat[S]. Jakarta: PB PERKENI, 2011, pp: 6 - 9.

[11] World Intellectual Property Organization (WIPO), International Bureau. International publication number: WO2009/036529 A1. Diabetes prophylaxis and treatment remedy and a method of getting it.

(2013 - 06 - 14 收稿 责任编辑: 王明)

(上接第 248 页)

[32] Carolin A Smith, Sheryl de Lacey, Michael Chapman, et al. Acupuncture to improve live birth rates for women undergoing in vitro fertilization: A protocol for a randomized controlled trial[J]. Trials, 2012, 13(60): 1 - 6.

[33] Smith C, Crowther C. The placebo response and effect of time in a trial of acupuncture to treat nausea and vomiting in early pregnancy[J]. Complement Ther Med, 2002, 10(4): 210 - 6.

[34] Smith C, Crowther C, Beilby J. Acupuncture to treat nausea and vomiting in early pregnancy: a randomized controlled trial[J]. Birth, 2002, 29(1): 1 - 9.

[35] Smith C, Crowther C, Beilby J. Pregnancy outcome following women's participation in a randomised controlled trial of acupuncture to treat nausea and vomiting in early pregnancy[J]. Complement Ther Med, 2002, 10(2): 78 - 83.

[36] Shin Takayama, Tetsuharu Kamiya, Masashi Watanabe, et al. Report on disaster medical operations with acupuncture/ massage therapy after the great east Japan earthquake[J]. Integrative Medicine Insights, 2012, 2012(7): 1 - 5.

[37] MacPherson H, Richmond S, Bland JM, et al. Acupuncture, Counseling, and Usual care for Depression (ACUDep): Study protocol for a randomized controlled trial[J]. Trials, 2012, 13(209): 1 - 7.

[38] Chang H, Kwon YD, Yoon SS. Use of acupuncture therapy as a supplement to conventional medical treatments for acute ischaemic stroke patients in an academic medical centre in Korea[J]. Complementary Therapies in Medicine, 2011, 19(5): 256 - 263.

[39] Park KH, Park YE, Yang TI, et al. Location of primary headaches of outpatients using newly developed meridian and acupuncture points of Korean hand therapy[J]. Medical Acupuncture, 2010, 22(2): 121 - 128.

[40] Andersen D, Løssl K, Nyboe Andersen A, et al. Acupuncture on the day of embryo transfer: a randomized controlled trial of 635 patients[J]. Reprod Biomed Online, 2010, 21(3): 366 - 72.

[41] Ishizaki N, Yano T, Kawakita K. Public status and prevalence of acupuncture in Japan[J]. Evidence - based Complementary and Alternative Medicine, 2010, 7: 4: 493 - 500.

[42] Sabine Moritz, Ming F. Liu, Badri Rickhi, et al. Reduced health resource use after acupuncture for low - back pain[J]. Journal of Alternative and Complementary Medicine, 2011, 17(11): 1015 - 1019.

[43] van den Berg I, Kaandorp GC, Bosch JL, et al. Cost - effectiveness of breech version by acupuncture - type interventions on BL 67, including moxibustion, for women with a breech foetus at 33 weeks gestation: A modelling approach[J]. Complementary Therapies in Medicine, 2010, 18(2): 67 - 77.

[44] Ytrehus IA, Norheim AJ, Emaus N, et al. Physicians become acupuncture patients - Not acupuncturists[J]. Journal of Alternative and Complementary Medicine, 2010, 16(4): 449 - 455.

[45] Borup L, Wurlitzer W, Hedegaard M, et al. Acupuncture as pain relief during delivery: a randomized controlled trial[J]. Birth, 2009, 36(1): 5 - 12.

[46] Lechleitner P, Walder A, Risslegger U, et al. Feasibility and acceptance of acupuncture treatment in a Department of Internal Medicine[J]. Deutsche Zeitschrift fur Akupunktur, 2005, 48(3): 12 - 17.

[47] Vas Ruiz J, Panadero Ruz D, Perez Blanco JL, et al. Acupuncture: An alternative in pain treatment[J]. Atencion Farmaceutica, 2003, 5(1): 18 - 24.

[48] Ternov NK, Buchhave P, Svensson G, et al. Acupuncture during childbirth reduces use of conventional analgesia without major adverse effects: A retrospective study[J]. American Journal of Acupuncture, 1998, 26(4): 233 - 239.

[49] Ivanov AI. Prophylaxis and treatment of motion disease by the application of plant patches on acupuncture zones[J]. Zhurnal Ushnykh Nosovykh i Gorlovykh Boleznei, 1998, (5): 30 - 37.

[50] Apostolopoulos A, Karavis M. Overeating: Treatment of obesity and anxiety by auricular acupuncture, an analysis of 800 cases[J]. Acupuncture in Medicine, 1996, 14(2): 116 - 120.

(2013 - 08 - 01 收稿 责任编辑: 徐颖)