

升陷汤加减辅助治疗慢性肺源性心脏病急性发作期的临床观察

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摘要 目的:探讨升陷汤加减辅助治疗慢性肺源性心脏病(CHPD)急性发作期的临床疗效及安全性。方法:将208例CHPD急性发作期患者按随机数字表法分为观察组和对照组,各104例。对照组患者给予西医综合治疗,包括吸氧、抗感染、祛痰、平喘、纠正呼吸及心力衰竭等。观察组患者在对照组基础上辅以升陷汤加减治疗,每日1剂,水煎服,连服7 d。观察两组患者治疗前后心肺功能情况、临床症状、体征积分、总积分,并比较两组患者临床疗效及不良反应发生情况。结果:两组患者治疗前心肺功能分级及一秒用力呼气容积(FEV₁)/预测值、FEV₁/用力肺活量(FVC)比较,差异无统计学意义($P>0.05$);治疗7 d后,两组患者心肺功能分级均显著好转,FEV₁/预测值、FEV₁/FVC明显升高,且观察组显著优于对照组,差异均有统计学意义($P<0.05$)。两组患者治疗前及治疗3 d后临床症状、体征及总积分组间比较,差异均无统计学意义($P>0.05$);治疗7 d后,观察组患者上述积分显著低于对照组,差异有统计学意义($P<0.05$)。观察组总有效率(98.1%)显著高于对照组(90.4%),差异有统计学意义($P<0.05$)。两组患者均未见明显不良反应发生。结论:升陷汤加减辅助治疗CHPD急性发作期疗效显著,能明显改善患者心肺功能及临床症状,且安全性较好。

关键词 升陷汤;慢性肺源性心脏病;急性发作期;临床疗效

Clinical Observation of Modified Shengxian Decoction in Adjunctive Treatment of Acute Episode of Chronic Pulmonary Heart Disease

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ABSTRACT OBJECTIVE: To explore the clinical efficacy and safety of modified Shengxian decoction in adjunctive treatment of acute episode of chronic pulmonary heart disease (CHPD). METHODS: 208 patients with acute episode of CHPD were divided into observation group and control group with 104 cases in each group according to random number table method. Control group was given comprehensive treatment of western medicine, including oxygen inhalation, anti-infective therapy, eliminating phlegm, relieving asthma, correcting respiratory and heart failure, etc. Observation group was additionally given modified Shengxian decoction, one dose a day, for 7 d, on the basis of control group. The cardiac and pulmonary function, clinical symptoms, sign score and total score were observed in 2 groups before treatment and after treatment. Clinical efficacy and the occurrence of ADR were compared between 2 groups. RESULTS: There was no statistical significance in FEV₁/predictive value and FEV₁/FVC between 2 groups before treatment ($P>0.05$); 7 d after treatment, cardiac functional grading of 2 groups were improved significantly, and FEV₁/predictive value and FEV₁/FVC were increased significantly; the observation group was significantly better than the control group, with statistical significance ($P<0.05$). There was no statistical significance in clinical symptoms and signs, total score between 2 groups before treatment and 3 d after treatment ($P>0.05$); 7 d after treatment, above score of observation group were significantly lower than that of control group, with statistical significance ($P<0.05$). Total effective rate of observation group (98.1%) was significantly higher than that of control group (90.4%), with statistical significance ($P<0.05$). No obvious ADR was found in 2 groups. CONCLUSIONS: The adjunctive therapy with modified Shengxian decoction is significantly effective for acute episode of CHPD, and can improve the cardiac and pulmonary function and clinical manifestations with good safety.

KEYWORDS Shengxian decoction; Chronic pulmonary heart disease; Acute episode; Clinical efficacy

慢性肺源性心脏病(CPHD)是指支气管、肺、胸廓或肺动脉病变引起肺循环阻力增高,肺动脉高压,导致右心室肥大及右心力衰竭的疾病,为临床常见的慢性病之一。CPHD急性发作期患者表现为咳嗽、咳痰、呼吸困难等症状,严重者可出现呼吸循环衰竭而危及生命。升陷汤是一种益气升陷类方剂,主治胸中大气下陷,气短不足以息,或努力呼吸,有似乎喘,或气息将停。有研究发现,升陷汤治疗慢性阻塞性肺疾病及各种心血管疾病疗效显著^[1-3]。但目前有关升陷汤治疗CPHD的报道少见,临床应用经验不足。为此,本研究探讨了升陷汤加减辅助治疗CPHD急性发作期的临床疗效及安全性,以期临床提供参考。

1 资料与方法

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1.1 纳入与排除标准

纳入标准:(1)诊断符合《内科学》(第7版)^[4]中CHPD急性发作期诊断标准者;(2)中医辨证为痰浊阻肺证或痰热郁肺证,符合《呼吸病学:喘证》诊断标准^[5]。排除标准:(1)合并有其他肺部疾病如肺癌、肺结核、间质性肺炎、尘肺者;(2)合并其他心脏疾病者;(3)合并严重脑血管疾病、肝肾功能不全、凝血功能障碍者;(4)病情危重需机械辅助通气者;(5)入院24 h内死亡者;(6)对中药成分过敏者。

1.2 研究对象

选取2014年1月—2015年12月在我院住院治疗的CHPD急性发作期患者208例,按随机数字表法分为观察组和对照组,各104例。其中,观察组患者男性68例,女性36例;年龄40~80岁,平均年龄(65.8±14.6)岁。对照组患者男性69例,女性35例;年龄40~78岁,平均年龄(64.2±15.8)岁。两组患者一般资料比较,差异均无统计学意义($P>0.05$),具有可比

性。本研究方案获得医院医学伦理委员会批准,患者知情同意并签署知情同意书。

1.3 治疗方法

对照组患者给予西医综合治疗,主要包括吸氧、抗感染、祛痰、平喘、纠正呼吸及心力衰竭等。观察组患者在对照组治疗基础上辅以升陷汤加减方剂治疗,在升陷汤基础上加用人参、当归、仙鹤草,减掉知母,即黄芪30g、人参30g、当归10g、桔梗10g、仙鹤草30g、柴胡5g、升麻5g。每日1剂,水煎服,连服7d。

1.4 观察指标及疗效评价标准

(1)观察两组患者治疗前后心功能分级情况、一秒用力呼气容积(FEV1)/预测值、FEV1/用力肺活量(FVC)。心功能分级采用美国纽约心脏病学会(NHYA)分级标准,由轻至重分为I~IV级。(2)观察两组患者治疗前及治疗后3、7d临床症状和体征积分。参考2002年版《中药新药临床研究指导原则》^[6]进行病情程度判断和评分。(3)观察两组患者临床疗效。疗效评价标准^[7]——治愈:临床症状体征总积分减少 $\geq 95\%$;显效:临床症状体征总积分减少 $70\% \sim < 95\%$;有效:临床症状体征总积分减少 $30\% \sim < 70\%$;无效:临床症状体征总积分减少 $< 30\%$ 。总有效=治愈+显效+有效。(4)观察两组患者不良反应发生情况。

1.5 统计学方法

采用SPSS 16.0软件对数据进行统计分析。计量资料以 $\bar{x} \pm s$ 表示,采用配对t检验;计数资料以例(率)表示,采用 χ^2 检验。 $P < 0.05$ 为差异有统计学意义。

2 结果

2.1 两组患者治疗前后心肺功能比较

治疗前,两组患者心功能分级及FEV1/预测值、FEV1/FVC比较,差异无统计学意义($P > 0.05$);治疗7d后,两组患者心功能分级均显著好转,FEV1/预测值、FEV1/FVC显著升高,且观察组显著优于对照组,差异均有统计学意义($P < 0.05$)。两组患者治疗前后心肺功能比较见表1。

表1 两组患者治疗前后心肺功能比较(例)

Tab 1 Comparison of cardiac and pulmonary function between 2 groups before and after treatment(case)

组别	n	时期	心功能分级,例				FEV1/预测值	FEV1/FVC
			I	II	III	IV		
观察组	104	治疗前	4	10	58	32	48.2±23.4	62.3±21.8
		治疗3d后	8**	46**	38**	12**	54.3±14.6**	72.8±16.7**
		治疗7d后	22**	68**	12**	2**	56.2±15.8**	78.6±14.2**
对照组	104	治疗前	5	12	57	30	47.8±24.2	64.6±23.6
		治疗3d后	6*	21*	51*	26*	51.2±11.2*	68.6±13.2*
		治疗7d后	14*	46*	36*	8*	52.6±11.6*	70.3±11.6*

注:与治疗前比较,* $P < 0.05$;与对照组比较,** $P < 0.05$

Note: vs. before treatment,* $P < 0.05$; vs. control group,** $P < 0.05$

2.2 两组患者治疗前后症状及体征积分变化

治疗前及治疗3d后,两组患者临床症状积分、体征积分及总分组间比较,差异均无统计学意义($P > 0.05$);治疗7d后,两组患者症状积分、体征积分及总分均显著降低,且观察组显著低于对照组,差异均有统计学意义($P < 0.05$)。两组患者治疗前后症状及体征积分比较见表2。

2.3 两组患者临床疗效比较

观察组患者总有效率为98.1%,显著高于对照组的90.4%,差异有统计学意义($P < 0.05$)。两组患者临床疗效比较见表3。

2.4 不良反应

两组患者治疗期间均未见明显不良反应发生。

表2 两组患者治疗前后症状及体征积分比较($\bar{x} \pm s$,分)

Tab 2 Comparison of clinical symptom and sign score between 2 groups before and after treatment ($\bar{x} \pm s$, score)

组别	n	时期	症状积分	体征积分	总积分
观察组	104	治疗前	14.6±3.2	7.8±2.2	22.4±5.6
		治疗3d后	8.2±2.4	4.3±1.6	12.5±4.1
		治疗7d后	4.3±1.4**	2.1±0.8**	5.4±2.2**
对照组	104	治疗前	14.2±3.4	7.6±2.2	21.8±5.5
		治疗3d后	8.8±2.6	4.6±1.8	13.4±4.5
		治疗7d后	6.8±1.3*	3.2±1.1*	10.0±2.5*

注:与治疗前比较,* $P < 0.05$;与对照组比较,** $P < 0.05$

Note: vs. before treatment,* $P < 0.05$; vs. control group,** $P < 0.05$

表3 两组患者临床疗效比较[例(%)]

Tab 3 Comparison of clinical efficacies between 2 groups [case(%)]

组别	n	治愈	显效	有效	无效	总有效率
观察组	104	2(1.9)	70(67.3)	30(28.8)	2(1.9)	102(98.1)*
对照组	104	0(0)	54(51.9)	40(38.5)	10(9.6)	94(90.4)

注:与对照组比较,* $P < 0.05$

Note: vs. control group,* $P < 0.05$

3 讨论

中医认为CHPD属于“喘证、肺胀”范畴,其发病机制较为复杂。临床上CHPD主要表现为咳嗽咳痰、喘息气促、胸部膨满、憋闷如塞,严重者合并发热、紫绀、昏迷、抽搐、出血、肢体浮肿等。中医辨证分为外寒里饮、痰浊阻肺、痰热郁肺、痰瘀阻肺、心肺肾气虚、心肾阳虚水泛、痰蒙神窍等,其中CHPD急性发作期以痰浊阻肺证和痰热郁肺证为主。CHPD的中医治疗原则为内外并治、标本兼顾,治外有疏风、散寒、宣肺、润燥、清热解毒等,治内以化痰、祛痰、补虚为主^[8]。

升陷汤出自《医学衷中参西录》,方剂组成有生黄芪、柴胡、桔梗、升麻,主治益气升陷。因本研究中患者为痰浊阻肺证或痰热郁肺证,伴有宗气下陷,加用人参、当归及仙鹤草,减掉黄芪。取人参补脾益肺、固脱生津,当归补血活血、调经止痛,仙鹤草补虚止血之功效。本研究结果显示,升陷汤加减辅助西医治疗能够快速促进心肺功能好转,有效保护缺血的心肌及其超微结构,减轻心肌损伤,提高心肌抗氧化能力,增强心肌活力,从而促进心脏功能恢复^[9]。

慢性阻塞性肺疾病(COPD)是CHPD的最常见病因,多存在不同程度的肺功能障碍,其中主要为肺通气功能障碍。FEV1/预测值及FEV1/FVC是临床上评价肺通气功能的主要指标^[10]。本研究结果显示,升陷汤加减辅助治疗有助于改善CHPD患者肺通气功能,与文献[1-3]报道一致。

本研究结果还显示,观察组患者的临床症状及体征评分较对照组患者下降明显,表明升陷汤加减辅助治疗CHPD急性发作期有助于快速缓解症状,改善体征,从而提高疗效。这与升陷汤中黄芪既善补气,又善升气,且其质轻松,中含氧气,与胸中大气有同气相求之效;柴胡为少阳之药,能引大气之陷者自左上升;升麻为阳明之药,能引大气之陷者自右上升;桔梗为药中之舟楫,能载诸药之力上达胸中,故用之为向导也,加之人参、当归、仙鹤草之补血补气之功效,诸药合用有助于缓解患者咳嗽、咳痰、紫绀、水肿、乏力等症状。

综上所述,升陷汤加减辅助治疗CHPD急性发作期疗效显著,能明显改善患者心肺功能及临床症状,且安全性较好。但本研究样本较小,其作用机制仍需扩大样本,进一步深入探讨。

参考文献

替吉奥联合 3D-CRT 与微波热疗治疗老年局部晚期食管癌的临床观察

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摘要 目的:观察替吉奥联合三维适形放射治疗(3D-CRT)与微波热疗治疗老年局部晚期食管癌的临床疗效及安全性。方法:将48例局部晚期老年食管癌患者按随机数字表法分为A、B、C组,各16例。A组患者给予局部3D-CRT,总剂量60~66 Gy,共治疗6~7周;B组患者在A组基础上口服替吉奥60 mg/(m²·d),bid,3周为1个疗程,直到放疗结束;C组患者在B组基础上行微波热疗,3周为1个疗程,直到放疗结束。比较3组患者放疗结束后,临床疗效、1年生存率及吞咽困难、体质量、卡氏(KPS)评分变化情况,并观察3组患者主要毒副反应(放射性食管炎、放射性肺炎、胃肠道反应、骨髓抑制)发生情况。结果:C组患者总有效率为93.75%,1年生存率为87.50%,吞咽困难缓解率为93.75%。明显高于A组的50.00%、50.00%、56.25%和B组的68.75%、68.75%、68.75%,差异均有统计学意义($P<0.05$)。3组患者体质量增加率及KPS评分增加率比较,差异均无统计学意义($P>0.05$)。C组患者放射性食管炎、肺炎发生率均显著低于A组和B组,差异均有统计学意义($P<0.05$);3组患者胃肠道反应、骨髓抑制发生率比较,差异均无统计学意义($P>0.05$)。结论:替吉奥联合3D-CRT与微波热疗能显著提高老年局部晚期食管癌的临床疗效和生存率,且毒副反应相对较低。

关键词 替吉奥;微波热疗;三维适形放疗;局部晚期食管癌;疗效;毒副反应

Clinical Observation of Tegafur Gimeracil Oteracil Potassium Combined with 3D-CRT and Microwave Hyperthermia in the Treatment of Elderly Patients with Local Advance Esophageal Cancer

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ABSTRACT OBJECTIVE: To observe clinical efficacy and safety of tegafur gimeracil oteracil potassium combined with 3D-CRT and microwave hyperthermia in the treatment of elderly patients with local advance esophageal cancer. METHODS: 48 cases of local advance esophageal cancer were divided into group A, B and C according to random number table method, with 16 cases in each group according to random number table method. Group A was given 3D-CRT with total dose of 60-66 Gy totally for 6-7 weeks; group B was additionally given tegafur gimeracil oteracil potassium 60 mg/(m²·d), bid, on the basis of group A 3 weeks for a course of treatment, until the end of radvotherapy; group C was additionally given thermotherapy on the basis of group B 3 weeks for a course of treatment, until the end of radvotherapy. Clinical efficacy, 1-year survival rate, dysphagia, weight and KPS score were compared among 3 groups, and the occurrence of toxic reactions (radioactive esophagitis, radioactive pneumonia, bone marrow suppression and gastrointestinal reaction) were observed in 3 groups. RESULTS: Total effective rate, 1-year survival rate and the remission rate of dysphagia of group C were 93.75%, 87.50% and 93.75%, which were significantly higher than those of group A (50.00%, 50.00% and 56.25%) and B (68.75%, 68.75% and 68.75%), with statistical significance ($P<0.05$). There was no statistical significance in the rate of weight gain and KPS score gain among 3 groups ($P>0.05$). The incidence of radioactive esophagitis and radioactive pneumonia in group C were significantly lower than in group A and B, with statistical significance ($P<0.05$); there was no statistical significance in the incidence of gastrointestinal reaction and bone marrow suppression among 3 groups ($P>0.05$). CONCLUSIONS: Tegafur gimeracil oteracil potassium combined with 3D-CRT and microwave hyperthermia in the treatment of elderly patients with local advance esophageal cancer further improves clinical efficacy and survival rate, but shows low incidence of toxic reaction.

KEYWORDS Tegafur gimeracil oteracil potassium; Microwave hyperthermia; 3D-CRT; Local advance esophageal cancer; Efficacy; Toxic reaction

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