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Auriculotherapy in relieving symptoms of constipation and improving quality of life for the elderly: a pilot project

Key Messages

1. Auriculotherapy was effective in relieving the symptoms of constipation and improving quality of life for elderly people.
2. Auriculotherapy had a significant time effect in relieving symptoms of constipation, a greater reduction in scores for symptoms of constipation and quality of life, and an increased number of bowel movements per week, compared with controls.
3. The methodology of this pilot project was appropriate for future studies on the effects of auriculotherapy for managing constipation in elderly people.

Introduction

Constipation is a common health problem among the elderly in residential care homes (RCHs). It impairs the general health and quality of life (QoL)[1] and is usually managed by laxatives and lifestyle modifications. Auriculotherapy (AT) is a traditional Chinese medicine treatment to alleviate pathological conditions in different parts of the body by stimulating the external surface of the auricle.[2] It has been effective in managing constipation, but major methodological flaws have been identified. Although no conclusion can be drawn regarding its effectiveness, AT appears to be an alternative treatment for constipation. This pilot project aimed to evaluate the effects of AT in relieving the symptoms of constipation and improving QoL for the elderly, and to test the feasibility and appropriateness of the study methodology.

Methods

This single-blind, randomised controlled study was conducted from September 2008 to August 2009. Ethical approval was granted by the Research and Ethics Committee of The Open University of Hong Kong. Permission was obtained from the superintendents of the participating RCHs. A total of 104 elderly persons with constipation from local RCHs were screened for eligibility. Those who (1) were aged >65 years, (2) met the Rome III diagnostic criteria for constipation,[3] (3) were cognitively competent with a score of ≥6 in the Abbreviated Mental Test, and (4) were able to communicate in Cantonese were included. Those who (1) had local lesions in or infection of the ears, or absence of ear(s), (2) had had previous AT within one year, (3) were free from major physical and psychiatric diseases, (4) were being treated with regular laxatives, (5) were undertaking a current bowel training programme, and (6) had an implanted electrical device in the body were excluded. After screening, 39 elderly persons were randomly assigned to receive AT for 3 weeks in an experimental (n=21) or a placebo (n=18) group. The former group used magnetic pellets with a magnetic flux density of ~200 Gauss, whereas the latter group used Semen Vaccariae. Both the participants and the research nurse were blinded to group assignments.

According to the perspective of Chinese medicine, participants were first assessed to be in an 'excess' or 'deficiency' syndrome with regard to constipation. Seven auricular acupoints for the large intestine, rectum, *San Jiao*, spleen, lung, sympathesis, and subcortex were stimulated, because of their positive effect in relieving the symptoms of constipation.[4] Both ears were treated alternately, with one ear taped each time (every 3-4 days), in order to avoid exerting persistent pressure on only one ear. The magnetic pellets and Semen Vaccariae were of comparable diameter, and the translucent auricular plasters were of the same size, colour, texture, and appearance.

During intervention, participants were instructed not to exert manual pressure to the taped acupoints, and to maintain their normal dietary habits and level of physical activity. The participants were also instructed to discontinue taking laxatives 3 days prior to the start of and throughout the intervention, failing which

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they would be withdrawn from the study. The possible side effects of AT were explained. The participants were closely monitored for undesirable effects.

The outcome variables were symptoms of constipation and QoL, which were measured using the Patient Assessment of Constipation – Symptom Questionnaire (PAC-SYM)[5] and the Patient Assessment of Constipation – Quality of Life Questionnaire (PAC-QOL),[6] respectively. The potential confounding variables (physical activity, dietary intake of fruits and vegetables) were monitored using the Physical Activity Questionnaire (PAQ). The drugs taken during the study period were reviewed. Outcomes were collected by face-to-face interviews on day 0 (baseline), day 10 (midway of intervention), day 21 (end of intervention), and then at the 1-month follow-up. The frequency of bowel movements and stool consistency were recorded daily 2 weeks before the intervention until after completion of the intervention.

Results

Of the 39 participants, 17 in the experimental group and 13 in the placebo group completed the intervention. The dropout rate was 23.1%; the reasons were perceptions of no benefit (n=4) and taking of laxatives (n=5).

Baseline characteristics of participants

The participants were of advanced age (mean age, 81; standard deviation [SD], 7.22 years) and mostly females (83.3%). Nearly 80% of them had co-morbidities and in receipt of regular medication. The mean duration of constipation was 4.9 (SD, 7.4) years. All participants were diagnosed to have the 'deficiency syndrome' of constipation. There were no significant differences in baseline characteristics and outcome variables in the two groups.

Effects of auriculotherapy in constipation

The effects of AT were evaluated using the mixed between-within subject analysis of variance. A modified intention-to-treat approach was adopted in which participants who had withdrawn from the study were not excluded so long as they had commenced the intervention. The missing data for the dropouts were replaced by the last observation. These dropouts were expected to be free of further benefit from the intervention.

For effects of the intervention on symptoms of constipation, there were no significant group effects ($F(1,37)=0.14$, $P=0.72$, $\eta_p^2=0.004$) and interaction effects ($F(3,111)=0.28$, $P=0.84$, $\eta_p^2=0.007$), but time effects ($F(3,111)=7.24$, $P=0.000$, $\eta_p^2=0.164$) were significant. Regarding QoL, there were also no significant group effects ($F(1,37)=0.04$, $P=0.85$, $\eta_p^2=0.001$) and interaction effects ($F(3,111)=0.51$, $P=0.68$, $\eta_p^2=0.014$), but time effects [$F(3,111)=5.72$, $P=0.00$, $\eta_p^2=0.134$] were significant.

According to the repeated measures analysis of variance, for PAC-SYM, there were significant time effects in the experimental group (Wilks' Lambda=0.43, $F(3,18)=7.83$, $P=0.001$, $\eta_p^2=0.57$) but not in the placebo group (Wilks' Lambda=0.77, $F(3,15)=1.47$, $P=0.264$, $\eta_p^2=0.227$). The differences between day 0 and day 21, and between day 0 and the 1-month follow-up were significant ($P<0.05$). For PAC-QOL, there were significant time effects in the placebo group (Wilks' Lambda=0.60, $F(3,15)=7.83$, $P=0.049$, $\eta_p^2=0.398$) but not in the experimental group (Wilks' Lambda=0.69, $F(3,18)=2.67$, $P=0.079$, $\eta_p^2=0.307$); only the difference between day 0 and the 1-month follow-up was significant ($P<0.05$). The potential confounding variables (physical activity and dietary intake of fruits and vegetables) had no mediating effects on outcome variables.

Although the between-group differences in symptoms of constipation and QoL were not significant, within-group differences (between baseline and post-tests) in terms of mean scores were significant (Tables 1 and 2). According to the mean scores of PAC-SYM and PAC-QOL in the two groups across time, the experimental group had more improvement than the placebo group in symptoms of constipation and QoL (Fig).

As there were no significant changes in drug history during the study period, a change of drug administration was not considered as a cofounder in interpreting the results. According to the daily bowel records of participants, the number of bowel movement per week increased by a mean of 0.33 (SD, 1.17) in the experimental group but decreased

Table 1. Assessment of Constipation – Symptom Questionnaire (PAC-SYM) scores of the 39 patients during the study period

Time	Mean±SD PAC-SYM scores							
	Total		Abdominal symptoms		Rectal symptoms		Stool symptoms	
	Experimental group	Placebo group	Experimental group	Placebo group	Experimental group	Placebo group	Experimental group	Placebo group
Baseline (day 0)	6.43±4.23	6.72±4.69	0.71±1.10	0.89±1.41	0.48±0.68	0.61±0.98	5.24±3.60	5.22±3.19
Midway of auriculotherapy (day 10)	5.10±4.36	5.06±4.58	0.48±0.98	0.83±1.47	0.29±0.64	0.22±0.65	4.33±3.44	4.00±3.31
End of auriculotherapy (day 21)	4.19±4.46	4.78±4.53	0.48±0.98	0.72±1.45	0.33±0.66	0.39±0.92	3.38±3.47	3.67±3.34
1-month follow-up	3.67±3.89	4.61±4.15	0.57±1.25	0.72±1.45	0.33±0.66	0.22±0.55	2.76±2.74	3.67±2.77
Day 10 – day 0	-1.33±3.32	-1.67±3.99	-0.24±0.62	-0.06±0.94	-0.19±0.40	-0.391±0.85	-0.90±3.55	-1.22±3.08
Day 21 – day 10	-0.90±2.95	-0.28±3.41	0.00±0.45	-0.11±0.96	0.05±0.22	0.17±0.51	-0.95±2.94	-0.33±2.81
1-month follow-up – day 21	-0.52±3.09	-0.17±3.68	0.10±0.94	0.00±0.84	0.00±0.32	-0.17±0.71	-0.62±2.77	0.00±3.36

Table 2. Assessment of Constipation – Quality of Life Questionnaire (PAC-QOL) scores of the 39 patients during the study period

Time	Mean±SD PAC-QOL scores									
	Total		Physical discomfort		Psychosocial discomfort		Worries and concerns		Satisfaction	
	Experimental group	Placebo group	Experimental group	Placebo group	Experimental group	Placebo group	Experimental group	Placebo group	Experimental group	Placebo group
Baseline (day 0)	20.14±7.87	19.22±10.91	2.00±1.90	1.83±2.36	1.00±1.70	0.94±2.07	5.86±3.02	4.78±5.17	11.29±4.24	11.67±2.83
Midway of auriculotherapy (day 10)	17.19±8.91	17.56±14.59	1.33±1.98	1.44±2.53	0.19±0.51	1.06±1.73	5.48±3.96	5.39±7.85	10.19±4.71	9.67±4.78
End of auriculotherapy (day 21)	14.52±8.09	16.50±10.73	1.14±1.90	1.00±2.35	0.33±0.66	0.50±1.54	4.48±3.31	5.28±6.02	8.57±4.12	9.72±3.06
1-month follow-up	14.95±8.18	15.83±11.74	1.29±2.08	1.61±2.38	0.33±0.91	0.44±1.46	3.95±3.37	4.11±5.14	9.38±4.34	9.67±4.27
Day 10 – day 0	-2.95±7.90	-1.67±7.77	-0.67±1.62	-0.39±1.24	-0.81±1.44	0.11±1.68	-0.38±3.07	0.61±4.63	-1.10±5.57	-2.00±4.60
Day 21 – day 10	-2.67±5.48	-1.06±8.56	-0.19±1.12	-0.44±1.10	0.14±0.79	-0.56±1.50	-1.00±1.97	-0.11±3.31	-1.62±4.02	0.06±4.26
1-month follow-up – day 21	0.43±6.65	-0.67±5.22	0.14±1.39	0.61±1.04	0.00±0.95	-0.06±0.87	-0.53±2.14	-1.17±2.57	0.81±3.97	-0.06±3.89

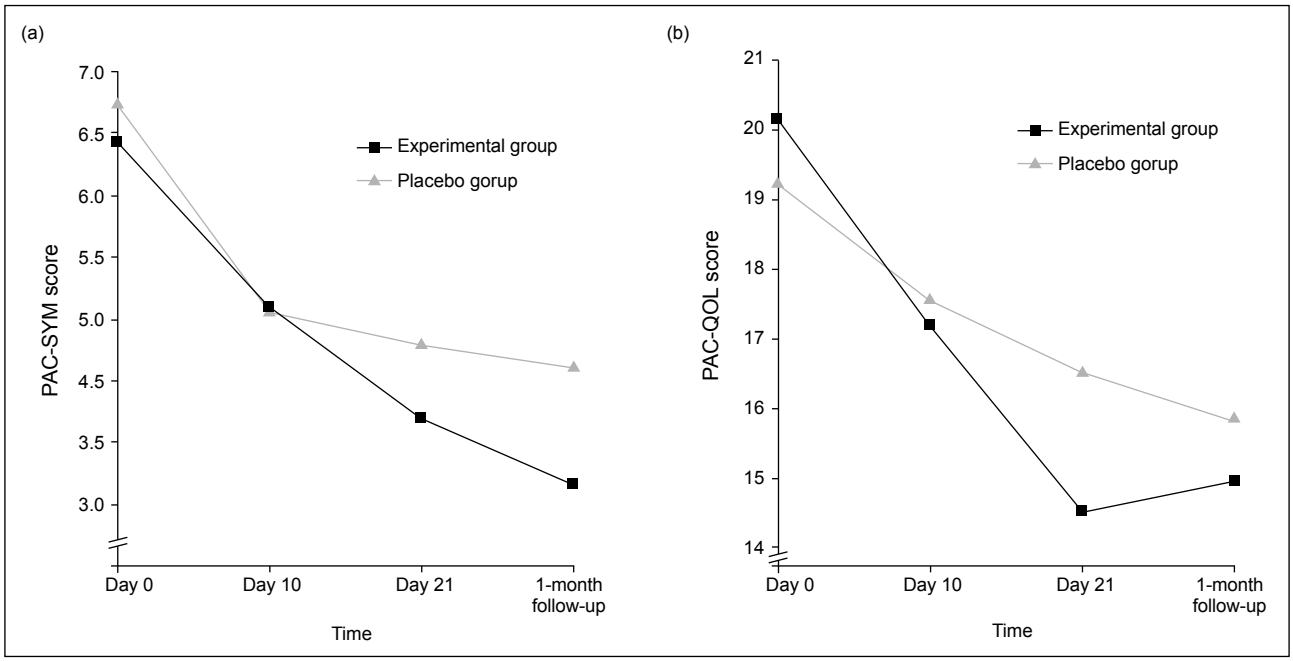

Fig. (a) Patient Assessment of Constipation – Symptom Questionnaire (PAC-SYM) and (b) Patient Assessment of Constipation – Quality of Life Questionnaire (PAC-QOL) mean scores across time for the experimental and placebo groups

by a mean of 0.4 (SD, 1.07) in the placebo group, whereas six and seven participants in the respective groups reported softer stools after the intervention. In addition, two and five participants in the respective groups reported mild, tolerable, and short-term itchiness of the ears after the intervention.

Discussion

Constipation is more common among females.[7] In this study, young older adults were under-represented; most participants were old older adults (mean age, 81 years). Nearly 80% of the participants had co-morbidities and in receipt of regular medication. Polypharmacy is a major factor contributing to constipation in elderly people.[7] All our participants were diagnosed to have the 'deficiency syndrome' of constipation. Thus, generalisation of results may be limited to old older adults with the 'deficiency syndrome' of constipation.

The non-significant group effects may be due to the small sample size. Only the experimental group had significant time effects in symptoms of constipation, whereas only the placebo group had significant time effects in QoL. According to the PAC-SYM and PAC-QOL scores, the experimental group had more improvement than the placebo group in symptoms of constipation and QoL. The additional magnetic effects may contribute to the better therapeutic effect in the experimental group.

The significant time effects in symptoms of constipation

in the experimental group indicated that the 21-day intervention period was sufficient to detect a significant time effect.

Many potential participants were excluded because they were unable to communicate in Cantonese or receiving laxatives. Thus, a longer recruitment period or a multi-centre trial may be necessary for future studies. In fact, many elderly people in RCHs had constipation despite taking laxatives. Omitting this particular exclusion criterion (laxatives taking) could have made the samples more representative. As the beneficial effects of AT in managing constipation were inconclusive in previous studies, it is not yet appropriate to withhold the usual care when a new intervention has not been proved to be more beneficial.[8] Therefore, future studies should shift their focus to investigating the complementary effects of AT in managing constipation, which would be more reality-oriented. To prevent the dropout of participants, clear instructions should be given to the participants to increase their compliance.

In this study, there was no control group that received only usual care. The pressure effects from the taped objects and the maturation effect of the disease were not cancelled out. Therefore, inclusion of a usual care group is recommended to address this shortcoming and improve the empirical evidence. Blinding of such intervention could be done by administering the AT but without taped objects on the plasters.

As the practitioner who conducted the intervention was not blinded, the interaction between the practitioner and participants might have affected the results reported by the participants (although they were blinded to their treatment assignment).

Conclusions

There were significant effects of AT across time, but not between groups. The experimental group had greater reduction in PAC-SYM and PAC-QOL scores and an increased number of bowel movement per week. The methodology of this study in terms of randomisation, intervention, data collection process, and instruments was appropriate for future studies on the effects of AT in managing constipation in elderly people.

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