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An Economic Evaluation of Thread Embedding Acupuncture for the Treatment of Lumbar Herniated Intervertebral Disc in a Randomized Controlled Clinical Trial

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ABSTRACT

Background: Lumbar herniated intervertebral disc (LHIVD) is a frequently presented condition/disease in Korean medical institutions. In this study, the economics of thread embedding acupuncture (TEA) was evaluated in a randomized controlled trial comparing TEA with sham TEA (STEA).
Methods: This economic evaluation was analyzed from a limited social perspective, and the per-protocol set was from a basic analysis perspective. The cost-effectiveness analysis was based on the change in visual analog scale score, and the cost-utility analysis was based on the quality-adjusted life years. The final results were expressed as the average cost-effectiveness ratio and incremental cost-effectiveness ratio, and furthermore sensitivity analysis was performed to confirm the robustness of the results observed.
Results: The cost-effectiveness analysis showed that TEA was 9,908 won lower than STEA, while the decrease in 100 mm visual analog scale score was 8.5 mm greater in the TEA group compared with the STEA group ($p > 0.05$). The cost-utility analysis showed that TEA was 9,908 won lower than STEA, while the quality-adjusted life years of TEA was 0.0026 years higher than STEA ($p > 0.05$). These results were robust in the sensitivity analysis, but were not statistically significant.
Conclusion: In treating LHIVD, TEA appeared to have cost-effectiveness and cost-utility compared with STEA. However, there were no significant differences between the groups in terms of cost, effectiveness, and utility indicators. Therefore, results must be interpreted prudently; this study was the 1st to conduct an economic evaluation of TEA for LHIVD.

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Introduction

A lumbar herniated intervertebral disc (LHIVD) may cause an inflammatory reaction due to the escape of the intervertebral nucleus which compresses the surrounding nerves, and result in low back and radiating pain [1]. Conservative treatment is considered in most cases, except for some cases where surgery is indicated such as severe loss of motor function [2,3]. Korean medicine treatment including acupuncture, pharmacoacupuncture, herbal medicine, and chuna therapy, can be considered a conservative treatment option, and the demand for these treatments has increased [4,5].

Thread embedding acupuncture (TEA) is a technique developed to enhance the treatment effect by introducing substances such as polydioxanone into acupoints [6]. Not only does this result in persistent stimulation of the acupoints, but it can also add chemical stimulation to increase the treatment effect [7]. TEA is widely used for musculoskeletal conditions/diseases including LHIVD [8,9].

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Research on TEA is currently lacking in robust evidence, and in the Korean Medicine Clinical Practice Guideline for the treatment of LHIVD, the use of TEA is recommended as a Grade B-C, and the level of evidence to support efficacy of treatment is low to moderate [10]. An economic evaluation of LHIVD treatment was reported, however, it was limited to a comparison between surgical and non-surgical treatments [11]. A randomized controlled clinical trial was conducted to examine the basis for the use of TEA in the treatment of LHIVD [12]. In this current study, an economic evaluation of TEA was conducted concurrently with a clinical trial to assess the economic feasibility of TEA as a treatment for LHIVD.

Materials and Methods

Analysis design

A randomized controlled trial (RCT) was conducted to determine the effectiveness of TEA treatment for LHIVD. Participants were randomly assigned to 2 groups, either TEA or sham TEA (STEA) treatment, and patients received 8 sessions, once a week. In both groups, either a 29-gauge, 40 mm, or a 29-gauge, 60 mm TEA or STEA needle (Hyundae Meditech, Wonju, South Korea) was used on 23 predefined acupoints. The patient took a prone position and the skin surface was sterilized prior to administration of TEA or STEA. In the STEA group, the thread was removed aseptically to prevent infection, and without the patients knowledge, to ensure blinding of the study to the patient.

This RCT had approval from the Institutional Review Boards of the institutions involved (KHUHGD: KHNMCOH 2016-09-006, KHUMC: 161216-HR-006, DUBOH: 2016-0012, DKMHDHU: DHUMC-D16015-PRO-02) [12].

Using data from the participants of the RCT an economic evaluation was conducted in parallel, and similar to the trial, the analysis period was a total of 7 weeks from the 1st treatment (Week 1) to the end of treatment (Week 8). The analysis groups for the economic evaluation were: Full Analysis Set (FAS), "The participants who were randomly assigned and received intervention at least once to obtain at least 1 piece of data," and Per Protocol Set (PPS), "The participants included in the FAS analysis who had completed the RCT with all the main outcomes within the analysis period."

In this study, with the PPS as the basic analysis perspective, cases with missing values within the analysis period were excluded.

Sensitivity analysis

The uncertainty of the results was assessed through sensitivity analysis (SA) of the various included parameters to confirm the robustness of the results observed [13]. The analysis perspective was the same limited social perspective as described for the basic analysis [14].

In SA1 and SA4, unlike the basic analysis, which assessed cost-effectiveness or cost-utility under PPS, additional FAS analysis was performed considering that this study was an economic evaluation, run in parallel to the RCT. Unlike the basic analysis, FAS analysis applied the last observation carried forward (LOCF) method (which estimated the most recent data as if it had been obtained at the time of the evaluation for missing values or participants who dropped out before the RCT was terminated) for a conservative evaluation. In SA2 and SA5, the median was similar to the typical cost. However, the use of mean-based analysis is an official strategy in policy making and widely used in practice. Therefore, analysis was based on the mean rather than the median value. In SA3, the analysis was conducted using the Oswestry disability index (ODI), which is the secondary outcome of this study, instead of the visual analog scale (VAS), which was the primary outcome.

Participants

In the RCT [12], participants were selected by the following criteria; (1) men or women aged 19 to 70 years; (2) patients whose magnetic resonance image or computed tomography image showed a severe bulging abnormality in the lumbar spine and corresponding symptoms of radiating pain; (3) patients who complained of low back pain and indicated more than 40 mm on the 100 mm VAS; and (4) patients who voluntarily participated and agreed to give signed informed consent, after hearing the details of the clinical trial.

The exclusion criteria were; (1) a history of surgery or congenital deformity in the lumbar spine; (2) suspected cauda equina syndrome; (3) tumors, fractures, and infections in the lumbar region; (4) a history of injections including steroids in the lumbar region within the last week; (5) being treated for psychiatric conditions/diseases, such as depression or schizophrenia; (6) other conditions that could interfere with the intervention, such as severe gastrointestinal disease, cardiovascular disease, high blood pressure, diabetes, kidney disease, liver disease, and thyroid dysfunction; (7) conditions unsuitable for TEA due to skin problems and hematological disorders (prothrombin time with an international normalized ratio > 2.0, or anticoagulant medication); and (8) pregnancy or other conditions unsuitable for TEA.

Costs

The analysis perspective of this study adopted the "Restricted social perspective" recommended by guideline [14]. Therefore, official medical costs, unofficial medical costs, transportation costs, and paid nursing costs were included in the cost estimation; however, indirect costs were excluded from the basic analysis, and the analysis was conducted as median-based value considering the distribution of cost data.

The official medical costs were calculated by the institution where the clinical trial was conducted [the Kyung Hee University Hospital, Gangdong (KHUHGD), Kyung Hee University Medical Center (KHUMC), Dongguk University Bundang Oriental Hospital (DUBOH), and Daegu Korean Medicine Hospital of Daegu Haany University (DKMHDHU)]. Transportation costs were defined as, "All costs incurred when a patient used transportation to visit a hospital for treatment." Information on unofficial medical costs, transportation costs, and paid nursing costs were collected through patient response.

Outcome measures

VAS

The severity of low back pain felt by the participants in the RCT was evaluated using the VAS which is a 100 mm scale. Since the primary outcome was the change in the severity of low back pain, the cost-effectiveness analysis was performed using the change which had occurred in the VAS score at the end of treatment, compared with the baseline VAS score. This was the effectiveness indicator.

ODI

A clinical trial evaluated disability in everyday situations caused by low back pain using the ODI [15], which was used as

a secondary outcome measure. In this economic evaluation, the SA was performed separately using the ODI, considering the uncertainty about the selection of effectiveness indicators, such as the VAS score in the cost-effectiveness analysis.

Quality-adjusted life years / EuroQol-5-Dimensions-5 Levels

The quality-adjusted life years (QALY) is the most commonly used outcome measure in economic evaluations, and was used in this study for evaluating cost-utility. Quality weight has been previously validated in Koreans, and many studies have been conducted; therefore, the QALY was calculated using the EuroQol-5-Dimensions-5 Levels (EQ-5D-5L) [16].

The quality weight of EQ-5D-5L values at Visit 1 (baseline, Week 1), Visit 4 (Week 4) and Visit 8 (end-point, Week 8) were collected in the RCT and were calculated as previously described [16]. The calculated EQ-5D-5L quality weight was measured sectionally through the area under the curve, and the median of the QALY was derived.

Statistical methods

Differences in general characteristics between the groups and changes in each outcome after treatment (from baseline) were compared using the independent t test. The statistical significance level was set at 0.05. For economic evaluation, cost-effectiveness, and cost-utility was evaluated by calculating the average cost-effectiveness ratio (ACER) and incremental cost-effectiveness ratio (ICER).

Results

Participants

In the RCT [12], there were 35 participants who met the inclusion criteria and were randomly assigned to a group. The study was powered to 80%, considering a dropout rate of 20%.

In the economic evaluation, based on the PPS analysis as the basic analysis, the analysis was conducted on a total of 60 participants, 30 each for the TEA and STEA groups, excluding the case where the outcomes were missing within the analysis period. In contrast, the FAS analysis conducted as a part of the SA applied the LOCF method to analyze a total of 70 participants, including 35 from the TEA group and 35 from the STEA group (including all cases where missing values occurred or the participant had dropped out before the clinical trial was terminated). The baseline characteristics in the PPS and FAS analysis are summarized in Table 1. There were no significant differences between the 2 groups ($p > 0.05$).

Costs

The costs for the entire analysis period are listed in Table 2. No intergroup statistical significance was observed for any of the cost items ($p > 0.05$). In the case of transportation costs, there were many missing responses from participants using subways and buses, or their own vehicle for transportation. Therefore, the round-trip cost for subways and buses was calculated to be 2,676 won (based on the 2018 Public Transportation Status Survey

Table 1. Baseline Characteristic Analysis of the Participants in the PPS and the FAS.

	PPS analysis			FAS analysis		
	TEA group (n = 30)	STEA group (n = 30)	p	TEA group (n = 35)	STEA group (n = 35)	p
Sex (male/female)	13/17	17/13	> 0.05	17/18	18/17	> 0.05
Age (y)	51.3 ± 8.4	54.0 ± 13.2	> 0.05	50.8 ± 8.7	53.1 ± 12.8	> 0.05
Screening VAS	64.2 ± 14.5	64.5 ± 14.6	> 0.05	64.7 ± 13.7	64.4 ± 15.0	> 0.05

* Data are presented as mean ± SD.
FAS, full analysis set; IQR, interquartile range; PPS, per protocol set; STEA, sham thread embedding acupuncture; TEA, thread embedding acupuncture; VAS, visual analog scale.

Table 2. Estimation of Costs for 7 Weeks of Treatment (unit: won).

		Official medical costs	Unofficial medical costs	Transportation costs	Paid nursing costs	Total costs
TEA	Median	150,020	0	18,732	0	157,360 (100,142-177,498)*
	Mean	193,984	0	20,787	0	214,771 ± 178,532†
STEA	Median	150,235	0	21,408	0	167,268 (69,000-486,220)*
	Mean	200,106	0	22,909	0	223,015 ± 174,949†

* IQR are presented in parentheses.
† Data are presented as mean ± SD.
IQR, interquartile range; STEA, sham thread embedding acupuncture; TEA, thread embedding acupuncture.

published by the Korea Transportation Safety Authority [17]), and for patients using their own cars, fuel was measured at 15.49 km/L (based on the 2018 Automotive Energy Consumption Efficiency Analysis published by the Korea Energy Agency [18]). Clinical trial designs have limited treatment, other than the intervention, resulting in no unofficial medical costs, and there were no cases of reimbursement of nursing costs.

Outcomes

VAS

The mean and median VAS scores for low back pain are shown in Table 3. At the end of the treatment, compared with the beginning, the median VAS score decreased by 29.0 mm in the TEA group and 20.5 mm in the STEA group, showing a greater reduction in the scale of subjective pain by 8.5 mm in the TEA group. However, this difference was not statistically significant ($p > 0.05$).

ODI

At the end of the treatment, compared with the beginning, the median value of the ODI decreased by 12.0 in the TEA group and 6.5 in the STEA group, showing a greater reduction in the TEA group. However, this difference was not statistically significant ($p > 0.05$; Table 4).

QALY / EQ-5D-5L

The result of calculating the quality weights of both groups for EQ-5D-5L are shown in Table 5. Over the analysis period, the TEA group maintained a higher EQ-5D-5L than the STEA group. However, there were no statistically significant differences between the 2 groups ($p > 0.05$).

Based on the quality weights of the EQ-5D-5L for 7 weeks of treatment, the QALY of the TEA group was 0.1010, and the STEA group was 0.0984. The QALY in the TEA treated group was 0.0026 higher compared with the STEA group. However, there were no statistically significant differences between groups ($p > 0.05$).

Economic evaluation analysis

Cost-effectiveness analysis

The cost-effectiveness analysis was performed without applying the model as a base-case analysis (Table 6). Compared with the costs of the 2 groups, TEA was 9,908 won lower than STEA for 7 weeks of treatment, while the decrease in mean VAS score at the end of the treatment, compared with the beginning, was 8.5 mm higher in the TEA group, compared with the STEA group. To reduce by a unit on the VAS, which was represented by the ACER, it cost 5,426 won for TEA treatment and 8,159 won for STEA treatment. In this study, a reduction of 20 mm on the VAS scale was defined as "Minimally clinically important change (MCIC)" [19], and for the ICER, a reduction of 20 mm on the VAS was -23,313 won. Therefore, TEA was considered to be more cost-effective than STEA because it was less expensive and more effective than STEA. However, there was no statistically significant difference in the VAS scores between the 2 groups; in the clinical trial design, the same cost was charged to both groups and the cost difference was not significant.

Compared with the costs of the 2 groups, TEA was 9,908 won

Table 3. The VAS Scores for Low Back Pain.

	Group	Mean ± SD	Median (IQR)	*p*
1 wk	TEA	64.7 ± 14.1	60.0 (53.0 – 72.0)	> 0.05
	STEA	65.3 ± 14.7	66.0 (50.0 – 80.0)	
8 wks	TEA	37.6 ± 22.6	31.5 (27.0 – 51.0)	> 0.05
	STEA	44.1 ± 18.1	49.0 (30.0 – 53.0)	
Δ VAS*	TEA	27.1 ± 20.4	29.0 (19.0 – 43.0)	> 0.05
	STEA	21.2 ± 19.4	20.5 (8.0 – 39.0)	

* VAS change: baseline (1 week) minus endpoint (8 weeks).
VAS, visual analog scale; IQR, interquartile range; STEA, sham thread embedding acupuncture; TEA, thread embedding acupuncture.

Table 4. The ODI Values for Low Back Pain.

	Group	Mean ± SD	Median (IQR)	*p*
1 wk	TEA	34.8 ± 12.9	31.6 (26.0 – 42.2)	> 0.05
	STEA	36.2 ± 14.6	33.0 (26.0 – 46.0)	
8 wks	TEA	23.1 ± 13.3	20.0 (15.6 – 26.0)	> 0.05
	STEA	26.5 ± 12.6	25.2 (16.0 – 32.0)	
Δ ODI*	TEA	11.7 ± 11.8	12.0 (6.0 – 16.0)	> 0.05
	STEA	9.7 ± 11.6	6.5 (0 – 20.0)	

* ODI change: baseline (1 week) minus endpoint (8 weeks).
ODI, Oswestry Disability Index; IQR, interquartile range; STEA, sham thread embedding acupuncture; TEA, thread embedding acupuncture.

Table 5. The Quality Weights of the EQ-5D-5L.

Wk	Group	Mean ± SD	Median (IQR)	*p*
1	TEA	0.671 ± 0.165	0.730 (0.646 – 0.795)	> 0.05
	STEA	0.656 ± 0.141	0.706 (0.646 – 0.762)	
4	TEA	0.718 ± 0.103	0.745 (0.682 – 0.776)	> 0.05
	STEA	0.683 ± 0.147	0.730 (0.646 – 0.763)	
8	TEA	0.759 ± 0.111	0.790 (0.730 – 0.809)	> 0.05
	STEA	0.731 ± 0.111	0.763 (0.677 – 0.795)	

EQ-5D-5L, EuroQol-5-Dimensions-5 Levels; IQR, interquartile range; STEA, sham thread embedding acupuncture; TEA, thread embedding acupuncture.

Table 6. Cost-Effectiveness Analysis of TEA for LHIVD.

Indicator	Group	Costs (won)	Incremental costs (won)	Δ VAS (mm)	Incremental Δ VAS (mm)	ACER (won/point)	ICER (won/point)
Δ VAS	TEA	157,360		29.0	8.5	5,426	-1,166
	STEA	167,268	9,908	20.5		8,159	

ACER, average cost-effectiveness ratio; ICER, incremental cost-effectiveness ratio; STEA, sham thread embedding acupuncture; TEA, thread embedding acupuncture; VAS, visual analog scale.

Table 7. Cost-Utility Analysis of TEA for LHIVD.

Indicator	Group	Costs (won)	Incremental costs (won)	QALY	IncrementalQALY	ACER (won/point)	ICER (won/point)
QALY	TEA	157,360		0.1010	0.0026	1,558,020	-3,810,769
	STEA	167,268	9,908	0.0984		1,699,878	

ACER, average cost-effectiveness ratio; ICER, incremental cost-effectiveness ratio; STEA, sham thread embedding acupuncture; TEA, thread embedding acupuncture; QALY, quality-adjusted life years.

lower than STEA for 7 weeks of treatment, while the decrease in the mean VAS score at the end of the treatment, compared with the beginning, was 8.5 mm higher in the TEA group compared with the STEA group. A reduction by 1 unit of the VAS, which was represented by the ACER, cost 5,426 won for TEA, and 8,159 won for STEA. In this study, a reduction of 20 mm in the VAS score was considered a MCIC [19], and for the ICER, the reduction of 20 mm in the VAS score was -23,313 won. Therefore, TEA was considered to be more cost-effective than STEA because it was less expensive and more effective than STEA. However, there was no statistically significant difference in VAS scores between the 2 groups; in the clinical trial design, the same cost was charged to both the groups and the cost difference was not significant.

Cost-utility analysis

The cost-utility analysis was performed without applying the model as a basic case analysis, and the results are shown in Table 7. Compared with the costs of the 2 groups, TEA was 9,908 won lower than STEA for 7 weeks of treatment, while the QALY of TEA was 0.0026 years higher. The ICER was -3.81 million won/QALY, which appeared to have more cost-utility for the TEA group compared with the STEA group. However, there was no statistically significant difference in the QALY values between the 2 groups, and in the clinical trial design, the same cost was charged to both groups and the cost difference was not significant.

SA1 - FAS analysis

Unlike the basic analysis with 30 participants in each group, in the PPS analysis, the FAS analysis applied the LOCF method to analyze a total of 70 participants, including 35 from the TEA group and, 35 from the STEA group (Table 8). For the costs, TEA was 6,611 won lower than STEA for 7 weeks of treatment, while the decrease in the VAS score at the end of the treatment, compared with the beginning, was 9.0 points higher in the TEA group compared with the STEA group.

To reduce by a unit in the VAS, which was represented by the ACER, it cost 5,382 won for TEA and 8,135 won for STEA. In this study, a reduction by 20 points on the VAS was a MCIC [19], and for the ICER, the reduction by 20 points on the VAS was -14,691 won. Therefore, the FAS analysis showed that the TEA group had a lower cost and higher effectiveness compared with the STEA group; TEA was considered to be more cost-effective compared with STEA, which was the same as the basic analysis results. However, there was no statistically significant difference in the

Table 8. The Sensitivity Analysis for the Cost-Effectiveness Analysis of TEA for LHIVD.

	Indicator	Group	Costs (won)	Incremental costs (won)	Δ VAS (mm) or Δ ODI (points)	Incremental Δ VAS (mm) or Δ ODI (points)	ACER (won/point)	ICER (won/point)
SA1	Δ VAS	TEA	156,090		29.0	9.0	5,382	-735
		STEA	162,701	6,611	20.0		8,135	
SA2	Δ VAS	TEA	214,771		27.07	5.9	7,934	-1,397
		STEA	223,015	8,244	21.17		10,534	
SA3	Δ ODI	TEA	157,360		12.0	5.55	13,113	-1,785
		STEA	167,268	9,908	6.45		25,933	

* SA1: FAS analysis, SA2: mean-based analysis, SA3: analysis by changing the outcome to ODI.
ACER, average cost-effectiveness ratio; ICER, incremental cost-effectiveness ratio; ODI, Oswestry Disability Index; QALY, quality-adjusted life years; STEA, sham thread embedding acupuncture; TEA, thread embedding acupuncture; VAS, visual analog scale; SA, sensitivity analysis.

Table 9. The Sensitivity Analysis for the Cost-Utility Analysis of TEA for LHIVD.

	Indicator	Group	Costs (won)	Incremental costs (won)	QALY	Incremental QALY	ACER (won/QALY)	ICER (won/QALY)
SA4	QALY	TEA	156,090		0.1014	0.0030	1,539,349	-3,302,667
		STEA	162,701	6,611	0.0984		1,653,465	
SA5	QALY	TEA	214,771		0.0968	0.0038	2,218,089	-2,169,474
		STEA	223,015	8,244	0.0930		2,398,011	

* SA4: FAS analysis, SA5: mean-based analysis.
ACER, average cost-effectiveness ratio; ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life years; STEA, sham thread embedding acupuncture; TEA, thread embedding acupuncture; SA, sensitivity analysis.

VAS scores between the 2 groups ($p > 0.05$), and in the clinical trial design, the cost difference was not significant because the same cost was charged to the 2 groups.

SA2 - mean-based analysis

The results of the analysis based on the mean are presented in Table 8. In terms of costs, TEA was 8,244 won lower compared with STEA for 7 weeks treatment, while the decrease in the VAS score at the end of the treatment, compared with the beginning, was 5.9 points higher in the TEA group compared with the STEA group. To reduce by a unit of the VAS, which was represented by the ACER, it cost 5,382 won for TEA and 8,135 won for STEA treatment. In this study, a reduction of 20 points in the VAS score was a MCIC [19], and for the ICER, the reduction of 20 points of the VAS was -27,946 won. Therefore, the mean-based analysis showed that the TEA group had a lower cost and higher effectiveness compared with the STEA group, which was considered to be more cost-effective compared with STEA, which was the same as the basic analysis results. However, there was no statistically significant difference in the VAS scores between the 2 groups ($p > 0.05$), and in the clinical trial design, the cost difference was not significant because the same cost was charged to the 2 groups.

SA3 - analysis by changing the outcome measure to the ODI

In this analysis, even if the outcome measure had changed to the ODI instead of the VAS, the intention was to determine whether the results were the same, and to report the robustness of the results (Table 8). For the costs, the TEA was 9,908 won lower compared with STEA for 7 weeks of treatment, while the decrease in the ODI value at the end of the treatment, compared with the beginning, was 5.55 points higher in the TEA group compared with the STEA group. The MCIC was set to an ODI value decrease by 10 points [19], and for the ICER, the ODI 10 point reduction was -17,852 won. Therefore, when changing the outcome to the ODI, the analysis showed that the TEA group has lower cost and higher effectiveness compared with the STEA group; TEA was considered to be more cost-effective compared with STEA, which was the same as the basic analysis results. However, there was no statistically significant difference in the ODI reduction between the 2 groups ($p > 0.05$), and in the clinical trial design, the cost difference was not significant because the same cost was charged to the 2 groups.

SA for cost-utility analysis

SA4 - FAS analysis

The analysis results are listed in Table 9. Compared with the

costs of the 2 groups, TEA was 6,611 won lower compared with STEA for 7 weeks of treatment, while the QALY of TEA was 0.0030 years higher. The ICER was -3,302,667 won/QALY, still negative, which appears to have more cost-utility for the TEA compared with the STEA, which is the same as the basic analysis results. However, there was no statistically significant difference in the QALY values between the 2 groups, and in the clinical trial design, the same cost was charged to both groups and the cost difference was not significant.

SA5 - mean-based analysis

The results of the analysis based on the mean are presented in Table 9. The cost of TEA was 8,244 won lower compared with STEA for 7 weeks of treatment, while the QALY of TEA was 0.0038 years higher. The ICER was -2,169,474 won/QALY, still negative, which appeared to present with more cost-utility for the TEA compared with the STEA, and this was the same as the basic analysis results. However, there was no statistically significant difference in the QALY values between the 2 groups, and in the clinical trial design, the same cost was charged to both groups and the cost difference was not significant.

Discussion

Economic evaluation is the analysis of the economic efficiency of each alternative by simultaneously comparing costs and outcomes for several alternatives, including cost-effectiveness, cost-utility, cost-minimization, and cost-benefit analysis. In the healthcare field, economic evaluations are performed to efficiently use limited medical resources, reduce medical costs, and enhance the healthcare decision-making process [20].

Economic evaluation results are expressed as the ACER or the ICER. The ACER is an indicator of the average cost per unit of effectiveness for each alternative, which can be obtained by dividing the cost for each alternative by the effectiveness of each alternative (ACER = health care cost/clinical outcome). The ICER is an indicator of the cost per unit of effect, and the increase in the cost compared with the comparative alternative which is divided by the increase in effect (ICER = Δ cost/Δ effect) [14].

In contrast, economic evaluation is bound to imply some degree of uncertainty due to the lack of available data and the absence of a single methodology. Therefore, SA was performed to confirm the robustness of the results observed [13].

In this study, the economics of TEA in the treatment of LHIVD was analyzed using cost-effectiveness and cost-utility analyses. The analysis showed that TEA had cost-effectiveness and cost-utility compared with STEA, and the same results were confirmed by the SA. However, there was no statistical significance between the 2 groups in cost, effectiveness, and utility indicators; therefore, these results should be interpreted cautiously and the study should be viewed as an exploratory study. No statistically significant differences observed between the TEA and STEA groups were assumed to be due to the size of the study, and the comparative alternatives are TEA and STEA; therefore, the same cost was charged in the clinical trial design [21]. It was also based on the patient's report in estimating transportation costs, and the missing items were estimated using secondary sources, which may bring uncertainty to the process.

To confirm the significance of the economics of TEA for LHIVD, large-scale RCTs must be conducted in the future, and detailed data collection on costs must be conducted, resulting in robust economic evaluation results.

Nevertheless, so far, studies on TEA for LHIVD have been reported as case reports [22], RCTs [8], and systematic reviews [23]; however, no study with an economic evaluation in parallel to a RCT has been reported. Therefore, it is meaningful to report economic evaluation through the cost-effectiveness and cost-utility analysis of TEA treatment for LHIVD for the 1st time. It is also significant that it can be used as a basis for future economic evaluation studies of LHIVD and TEA.

Conclusion

Based on data from participants in the RCT that investigated the effectiveness of TEA on LHIVD, an economic evaluation of TEA for LHIVD was conducted. As a result, it was observed that TEA has cost-effectiveness and cost-utility compared with STEA, and the results were maintained in the SA, however, since there were no significant differences in cost, effectiveness, and utility indicators, this result should be interpreted cautiously. Perhaps there was no statistical significance because the sample size was limited, and both the TEA and STEA groups were equally charged in the clinical trial design. Therefore, the results need to be interpreted prudently, and large-scale RCTs are needed in the future to conduct a better economic evaluation.

Conflicts of Interest

The authors have no conflicts of interest to declare.

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Ethical Statement

This research did not involve any human or animal experiment.

References

[1] Vialle LR, Vialle EN, Suárez Henao JE, Giraldo G. LUMBAR DISC HERNIATION. Rev Bras Ortop (English Ed) 2010;45:17-22.
[2] Awad JN, Moskovich R. Lumbar Disc Herniations: Surgical versus Nonsurgical Treatment. Clin Orthop Relat Res 2006;443:183-197.
[3] Kapetanakis S, Chaniotakis C, Kazakos C, Papathanasiou JV. Cauda Equina Syndrome Due to Lumbar Disc Herniation: A Review of Literature. Folia Med 2017;59:377-386.
[4] Tang S, Mo Z, Zhang R. Acupuncture for lumbar disc herniation: A systematic review and meta-Analysis. Acupunct Med 2018;36:62-70.
[5] Furlan AD, Yazdi F, Tsertsvadze A, Gross A, Van Tulder M, Santaguida L et al. Complementary and alternative therapies for back pain II. Evid Rep Technol Assess (Full Rep) 2010;(194):1-764.
[6] Trautschold OC. A Literature Review on the Study of Moisture in Polymers. Tech Rep Literature Rev Stud Moisture Polymers 2016;20:93-113.
[7] Lee KH, Lee DH, Kwon KR, Park HS, Park YY. A Literary Study on Embedding Therapy. J Korean Pharmacopuncture Inst 2003;6:15-21.
[8] Sung WS, Hong Y, Jeon SR, Yoon J, Chung EK, Jo HG et al. Efficacy and safety of thread embedding acupuncture combined with acupuncture for chronic low back pain: A randomized, controlled, assessor-blinded, multicenter clinical trial. Medicine (Baltimore) 2020;99:e22526.
[9] Kim E, Kim YS, Kim YI, Jeon JH, Yoo HR, Park YC et al. Effectiveness and Safety of Polydioxanone Thread-Embedding Acupuncture as an Adjunctive Therapy for Patients with Chronic Nonspecific Neck Pain: A Randomized Controlled Trial. J Altern Complement Med 2019:25;417-426.
[10] Jun J, Cha Y, Lee JA, Choi J, Choi TY, Park W et al. Korean medicine clinical practice guideline of lumbar herniated intervertebral disc in adults: An evidence based approach. Eur J Integr Med 2017;9:18-26.

[11] Tosteson ANA, Skinner JS, Tosteson TD, Lurie JD, Andersson GB, Berven S et al. The cost effectiveness of surgical versus nonoperative treatment for lumbar disc herniation over two years: Evidence from the Spine Patient Outcomes Research Trial. Spine 2008;33:2108-2115.
[12] Goo BH, Ryoo DW, Kim EJ, Nam DW, Lee HJ, Kim JS et al. Clinical research on the efficacy and safety of thread-embedding acupuncture for treatment of herniated intervertebral disc of the lumbar spine: A protocol for a multicenter, randomized, patient-assessor blinded, controlled, parallel, clinical trial. Trials 2018;19:484.
[13] Limwattananon S. Handling uncertainty of the economic evaluation result: Sensitivity analysis. J Med Assoc Thai 2008;91:S59-65.
[14] Kim JH, Kwon HY, Hong JH, Lee TJ [Internet]. A Guideline for Economic Evaluation of Korean Medicine. G-KoM. 2018. Available from: https://nikom.or.kr/nckm/board/view.do?manage_idx=24&board_idx=662&menu_idx=32. [in Korean].
[15] Jeon CH, Kim DJ, Kim SK, Kim DJ, Lee HM, Park HJ. Validation in the cross-cultural adaptation of the Korean version of the Oswestry Disability Index. J Korean Med Sci 2006;21:1092-1097.
[16] Kim SH, Ahn J, Ock M, Shin S, Park J, Luo N et al. The EQ-5D-5L valuation study in Korea. Qual Life Res 2016;25:1845-1852.
[17] The Korea Transportation Safety Authority [Internet]. The 2018 Public Transportation Status Survey. 2018. Available from: http://stat.molit.go.kr/portal/cate/statFileView.do?hRsId=483&hFormId=&hSelectId=&sStyleNum=&sStart=&sEnd=&hPoint=&hAppr=. [in Korean].
[18] The Korea Energy Agency [Internet]. The 2018 Automotive Energy Consumption Efficiency Analysis. 2018. Available from: http://bpms.kemco.or.kr/transport_2012/pds/month_pds.aspx. [in Korean].
[19] Ostelo RWJG, de Vet HCW. Clinically important outcomes in low back pain. Best Pract Res Clin Rheumatol 2005;19:593-607.
[20] Taylor C, Jan S. Economic evaluation of medicines. Aust Prescr 2017;40:76-78.
[21] Zorginstituut Nederland [Internet]. Guideline for economic evaluations in healthcare. 2016. Available from: https://english.zorginstituutnederland.nl/publications/reports/2016/06/16/guideline-for-economic-evaluations-in-healthcare.
[22] Lee HG, Im JG, Yook TH, Kim JU. Case Report on 4 patients with Lumbar Disc Herniation Treated with Concurrent Embedding Therapy under Conventional Korean Medical Treatments. Korean J Orient Physiol Pathol 2013;27:124-129.
[23] Sung WS, Goo BH, Kim EJ, Nam DW, Kim TH, Park YC et al. Efficacy and safety of thread-embedding acupuncture for lumbar herniated intervertebral disc: A systematic review and meta-analysis. Eur J Integr Med 2020;39:101195.