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Real-world effectiveness and costs of vertical oscillatory pressure manipulation for low back pain

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Abstract

Introduction. Real-world evidence studies using routinely collected data, such as patient clinical records, are innovative ways of generating insight into the effectiveness of healthcare interventions. This study examined the effectiveness of vertical oscillatory pressure (VOP) on selected clinical outcomes for patients with low back pain (LBP) using routinely collected data.
Methods. Retrospective analysis was carried out on the medical records of patients diagnosed with LBP in a tertiary hospital in south-west Nigeria over a 10-year period. Clinical outcomes (pain intensity and functional disability) in patients who received VOP (n = 201) for their LBP were compared with controls that had traditional physiotherapy (TP) (n = 138) in a routine clinical setting. Total costs of intervention were estimated in terms of direct and indirect costs.
Results. There were significant differences within group (from baseline to 4th and 8th week of intervention) for the VOP group in pain intensity (p = 0.001) and functional disability (p = 0.001). However, TP group showed no significant differences in pain intensity and functional disability across baseline and week 8 of the study. There was a significant difference in pain intensity (2.95 ± 1.38 vs. 4.16 ± 2.48; p = 0.013) between VOP and TP at week eight. A higher direct and indirect costs associated with VOP compared with TP (both p = 0.042).
Conclusions. The findings of this study suggest that VOP is an effective intervention for LBP in the 'real-world'. VOP is more effective compared to TP on its effect on pain intensity over time.
Key words: real world evidence, low back pain, cost, vertical oscillatory pressure

Introduction

Low back pain (LBP) is a global public health problem [1], affecting approximately 70–85% of individuals at some point in their lives [2, 3], causing significant disability and loss of time from work [4]. It is a source of significant economic burden to individual, families, communities, industry and governments [5, 6]. LBP is described as a symptom and not a disease [7] often characterized by pain and discomfort [8].

Owing to the enormous toll of LBP ranging from physical to economic [5, 6], there has been a proliferation of approaches aimed at ameliorating the burden associated with the condition. Largely, these approaches are classified as non-conservative and conservative. Of the conservative management of LBP, physiotherapy plays a significant role [9]. In the entire variety of physiotherapy for LBP, a wide range of interventions and techniques are widely reported in the literature [10–13]. Some of these include cryotherapy, ultrasound, exercises, spinal manipulations, massage, and traction [14–17]. Based on evidence, guidelines for LBP have recommended exercise programs and spinal manipulation as effective approaches for managing chronic LBP [18–21]. These clinical practice guidelines recommended manual therapy as first line management for both acute and chronic LBP. As there is no consensus on the best intervention from the recommended approaches, there has been a proliferation of randomized controlled trials (RCTs) aimed at generating evidence on the best or most effective approaches to managing LBP.

Randomized controlled trials are the main source of evidence on effectiveness or efficacy of interventions and are regarded as the "gold standard" for evaluating treatment outcomes [22, 23]. However, findings from such studies cannot be generalized to real life settings [24, 25]. Despite this, the pride of place of RCTs in evidence generation about interventions, there is still a gap between RCTs and real-world outcomes [26]. For example, RCTs have strict inclusion and exclusion criteria, limited duration of follow up, and sometimes inadequate sample sizes, meaning that protocol driven findings, and thus their applicability to real-life setting, are limited [27, 28].

Consequently, there is strong advocacy for real-world evidence studies [29, 30]. Researchers from the United States (US) Food and Drug Administration (FDA) define real-world evidence (RWE) as: Information on healthcare derived from multiple sources outside usual clinical research settings, including electronic medical records (EMRs), claims and billing data, product and disease registries and data gathered through personal devices and health applications. Real world studies can be observational or descriptive, that is non-interventional, or they can evaluate therapeutic interventions in usual care settings [31]. It also includes medical records, electronic health records, registries and databases studies [29].

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Different fields of medicine are embracing real-world studies as a new concept in validating evidence, especially, those generated from RCTs; for example, there is ample literature on RWE in pharmaceutical studies [32, 33], while there are emerging studies in oncology [34], health policy making [35], and health care technologies [36]. However, there seems to be an apparent dearth of RWE studies in physiotherapy, except for a study on RWE of treatment of fibromyalgia by [37]. As a result, there is need to validate physiotherapy interventions that are adjudged to be effective in research settings in the real-world clinical settings.

Manipulative therapy is one of the effective approaches in the management of LBP [17, 38]. Common manipulative therapies with reported effectiveness include spinal traction, rotation manoeuvres, flexion manoeuvres and hyper-extension [38], strain counter strain [17], lumbar rotatory technique, vertical oscillatory pressure (VOP) [39]. VOP is a common form of manipulative therapy among physiotherapists in Nigeria, especially among those trained in the Obafemi Awolowo University, Nigeria, the institution of the progenitor of the technique (Prof Emeritus V.C.B. Nwuga). The technique involves application of gentle vertical manipulative thrust on the vertebrae [40, 41]. Based on RCTs, VOP has been reported to be effective in relieving pain in patients with mechanical LBP [39, 40]. However, there is lack of empirical analysis of evidence of VOP in LBP, just as in other manual therapies, in real-world clinical settings. The objective of this study was to evaluate the effectiveness of VOP and associated costs as an intervention for patients with LBP in real-world.

Subjects and methods

Design and setting

This retrospective study was based on a 10-year review (June 2009 to May 2018) of medical records of patients who received VOP for the management of their LBP at the Outpatient Clinic of the Physiotherapy Department, Obafemi Awolowo University Teaching Hospitals Complex, Ile-Ife (OAUTHC). Records of patients with a physician diagnosis of LBP and who have been managed with VOP for LBP were included.

The intervention arms were those who had VOP for their LBP. The control arm included those who received other interventions, such as cryotherapy, soft tissue mobilization, electrotherapy, lumbar oscillatory rotation (LOR), sacroiliac joint manipulation, postural correction, transcutaneous electrical nerve stimulation, electrical muscle stimulation etc. The primary outcomes of interest in both groups were pain and disability, while cost was a secondary outcome. We estimated the sample size using a descriptive retrospective study sample size calculation with the assumption that 5% of the population receiving VOP at a precision of 95% CI of ± 0.03 [42]. The minimum sample size required was 200 per group.

Procedure

Case files of all patients with LBP were retrieved from the records office of the Physiotherapy Department of OAUTHC, Ile-Ife, Nigeria within the period of June 2009 to May 2018. Data was gleaned on socio-demographic (age, sex, occupation, education and marital status) and clinical (location, onset, duration, and recurrence) characteristics. The records were sorted for conventional measures (verbal rating scale for pain assessment and Roland Morris Disability Questionnaire for disability assessment) used to assess the effectiveness of VOP pre and post treatment, and other adjunct therapies used in the management of LBP. In addition, associated treatments and types and duration of the treatment received were gleaned. Also, information on the costs of delivering the intervention was obtained by reviewing the price list of each intervention during the periods the treatments were received.

We obtained the direct cost (cost of physiotherapy intervention) in Nigeria Naira for each patient from the price list as at the time the treatment were received and then estimated the indirect cost of intervention using the Heinrich method of calculating cost [43]. The total costs were determined from the addition of direct and indirect costs. The estimated indirect cost includes: cost of transportation to clinic, caregiver fee and productivity loss from missed work and physiotherapist time. Also, the formula states that the total cost was five times the direct costs.

Total cost = Direct cost + Indirect cost
Total cost = 5 * Direct cost
Therefore; Indirect cost = 4 * Direct cost

Data analysis

Data was summarized using descriptive statistics of mean and standard deviation, percentage, and tables. Chi-square and Fisher's exact tests were used to examine categorical variable associations. Inferential statistics of Friedman's and Mann–Whitney test were used to assess the effect of the intervention. Alpha level was set at $p < 0.05$. IBM SPSS version 23.0 was used for the data analysis.

Ethical approval

The research related to human use has complied with all the relevant national regulations and institutional policies, has followed the tenets of the Declaration of Helsinki, and has been approved by Ethics and Research Committee of the Obafemi Awolowo University Teaching Hospitals Complex, Ile-Ife, Nigeria (approval No.: ERC2018/10/08). Permission to undertake the study was obtained from the Record Unit of the Physiotherapy Department of OAUTHC. The medical records were anonymized without the names and any identifiable patient information.

Informed consent

Informed consent has been obtained from all individuals included in this study.

Results

A total of three hundred and thirty-nine case files of patients with LBP were retrieved and 201 received VOP while 138 received TP. A total of 41% of the retrieved case files had at least one element of incomplete information. The mean age of the participants was 53.7 ± 14.7 years. The participants that had VOP were comparable in age (years) with their counterparts who received TP for the management of their LBP (54.1 ± 13.6 vs. 53.2 ± 16.2; $p = 0.603$).

The frequency of use of VOP for the treatment of LBP over a period of 10 years was 59%. The pattern of use of VOP was shown in Tables 1. There was no significant association between the use of VOP and each of the sex ($p = 0.454$), neighbourhood status ($p = 0.230$) and occupations ($p = 0.697$). The results showed that VOP was often used significantly in combination with cryotherapy ($\chi^2 = 26.059$; $p = 0.001$) and LOR ($\chi^2 = 5.744$; $p = 0.017$).

The real-world effectiveness of VOP and TP assessed in terms of pain intensity and functional disability were presented in Table 2. The results showed that there was a statistically

Table 1. Pattern of use of VOP with other modalities and by demographics

Variable	VOP use			
	Yes *n* (%)	No *n* (%)	χ^2	*p*-value
Sex				
Male	103 (51%)	65 (47%)	0.562	0.454
Female	98 (49%)	73 (53%)		
Neighbourhood				
Lower	45 (22%)	42 (30%)	2.941	0.230
Middle	133 (66%)	80 (58%)		
Higher	23 (11%)	16 (12%)		
Occupation				
Managers	4 (2%)	1 (0.7%)		0.697‡
Professionals	84 (40%)	48 (35%)		
Clerical support workers	1 (0.5%)	0 (0%)		
Sales and sales workers	49 (23%)	31(22%)		
Skilled agricultural forest and fishery workers	8 (4%)	10 (7%)		
Craft and related trade workers	6 (3%)	3 (2%)		
Plants and machine	2 (1%)	2 (1%)		
Others	52 (25%)	40 (29%)		
No indices	3 (1%)	4 (3%)		
Cryotherapy	184 (92%)	97 (70%)	26.059	0.001*
Soft tissue mobilization	193 (96%)	130 (94%)	0.601	0.438
Infrared rays	121 (60%)	83 (60%)	0.001	0.992
Short wave diathermy	36 (18%)	26 (19%)	0.047	0.828
Exercises	139 (69%)	91 (66%)	0.387	0.534
Ultrasound	39 (19%)	17 (12%)	2.978	0.084
Traction	43 (21%)	32 (23%)	0.153	0.696
Lumbar oscillatory rotation	49 (24%)	19 (14%)	5.744	0.017*
Sacroiliac joint manipulation	46 (23%)	21 (15%)	3.034	0.084
Postural correction	12 (6%)	8 (6%)	0.004	0.947
Transcutaneous electrical nerve stimulation	6 (3%)	4 (3%)	0.002	0.963
Lumbar corset	13 (7%)	7 (5%)	0.287	0.592

VOP – vertical oscillatory pressure, ‡ *p* is for Fisher's exact test, * significance
Occupation grouping was done according to the International Standard Classification of Occupations (ISCO). Residential neighbourhood was classified as low (deprived), middle (average) and high (better-off) based on urban and regional planning descriptors of settlements in this study setting [44].

Table 2. Real world effectiveness of VOP and TP in terms of pain and disability

Variable	Baseline (mean ± *SD*)	4th week (mean ± *SD*)	8th week (mean ± *SD*)	Test statistic[a]	*p*-value
VOP					
Pain	6.74 ± 1.56	4.60 ± 1.50	2.95 ± 1.38	185.685	0.001*
Disability	13.6 ± 2.65	7.03 ± 2.30	5.47 ± 2.54	58.107	0.001*
TP					
Pain	5.20 ± 3.70	2.90 ± 2.07	2.20 ± 2.28	4.429	0.109

VOP – vertical oscillatory pressure, TP – traditional physiotherapy
* significance, [a] Friedman's test

Table 3. Comparison of age, pain duration and the effect of VOP and TP on pain and disability at the 4th and 8th weeks

Variable	VOP (mean ± *SD*)	TP (mean ± *SD*)	*U*	*p*-value
Week 4				
Pain	4.60 ± 1.50	4.03 ± 2.20	805.50	0.177
Disability	6.95 ± 2.32	27.00 ± 37.64	42.00	0.415
Week 8				
Pain	2.95 ± 1.38	4.16 ± 2.48	875.00	0.013*
Disability	5.47 ± 2.54	no data		
Confounder				
Age (years)	54.1 ± 13.6	53.2 ± 16.2	–0.520	0.603
Pain duration (weeks)	12.4 ± 19.3	12.5 ± 21.2	13442	0.629

VOP – vertical oscillatory pressure, TP – traditional physiotherapy
* significance

Table 4. Regression analysis of associations among age and pain duration as possible multiple covariates on VOP intervention outcome

Variable	Unstandardized coefficients		*p*-value
	B	Std. Error	
Week 4			
(Constant)	4.052	0.648	0.001
Age	0.007	0.010	0.475
Pain duration	0.001	0.001	0.159
Cryotherapy combine with VOP	1.461	1.183	0.219
LOR combine with VOP	–0.089	0.354	0.803
Cryotherapy and LOR combine with VOP	–2.193	1.313	0.098
Week 8			
(Constant)	1.900	0.680	0.006
Age	0.018	0.011	0.110
Pain duration	4.069×10^{-6}	0.001	0.996
Cryotherapy with VOP	2.878	1.235	0.021
LOR with VOP	0.455	0.363	0.212
Cryotherapy and LOR with VOP	–3.114	1.342	0.022

VOP – vertical oscillatory pressure, LOR – lumbar oscillatory rotation

Table 5. Costs of treatment of LBP

Cost (₦)	VOP (mean ± *SD*)	TP (mean ± *SD*)	*U*	*p*-value
Direct cost	7599.50 ± 3588.95	6901.09 ± 3279.51	12087.5	0.042
Indirect cost	30398.01 ± 14355.81	27604.35 ± 13118.03	12087.5	0.042
Total costs	37997.51 ± 17944.76	34505.43 ± 16397.53	12087.5	0.042

LBP – low back pain, VOP – vertical oscillatory pressure, TP – traditional physiotherapy
₦ 365 = $ 1

significant difference in pain ($p = 0.001$) and disability ($p = 0.001$) for VOP from baseline to 8 weeks post-intervention. However, there was no statistically significant difference in pain ($p = 0.109$) for TP from baseline to 8 weeks post-intervention. There was a lack of data on the effect of TP on disability.

The comparison between VOP and TP effect on pain and disability are shown in Table 3. The results showed statistically significant difference between VOP and TP effect on pain at week 8 (2.95 ± 1.38 vs. 4.16 ± 2.48; $p = 0.013$) but not at week 4 (4.59 ± 1.49 vs. 2.90 ± 2.07; $p = 0.177$).

Further analysis was performed to elicit possible confounders of the outcomes observed in the study. As such, age and pain duration of both groups were compared. However, no significant differences were found between the groups (all $p > 0.05$) (Table 3). Nonetheless, a linear regression analysis was used to examine the associations among age, pain duration, receiving cryotherapy and/or LOR as possible, as well as multiple covariates on intervention outcomes on pain at the mid and end points of the interventions, respectively. The findings indicated that age and pain duration were not

significant confounders of the outcome of the interventions on pain (all $p > 0.05$) but receiving cryotherapy with or without LOR was ($p < 0.05$) (Table 4).

In addition, there was significant difference in the direct (7599.50 ± 3588.95 vs. 6901.09 ± 3279.51), indirect (30398.01 ± 14355.81 vs. 27604.35 ± 13118.03) and total (37997.51 ± 17944.76 vs. 34505.43 ± 16397.53) costs of patients that were treated with VOP and TP ($p = 0.042$) (Table 5).

Discussion

To our knowledge, this is the first study to examine the real-world effectiveness and costs of VOP in the physiotherapy management of patients with LBP. From the study, it was found that VOP was commonly used for patients with LBP (59%) over a 10-year period. The mean age of the patients in this study was 53.7 ± 14.7 years. This age is within the age bracket in which LBP is confirmed to be preponderant [5]. A systematic review by Meucci et al. [45] found that LBP was around three to four times higher in individuals over 50 years compared to those aged 18 to 30 years.

The study revealed that VOP led to significant reduction in pain and disability in patients with LBP. There is increasing evidence on the efficacy of VOP in LBP stemming mainly from RCTs [39, 46, 47]. Typically, findings from RCTs are used to ascertain evidence for efficacy or effectiveness of interventions [22, 25]. Since the evolution of VOP, there has been an effort at generating evidence for its effectiveness. Nwuga [39] found that spinal mobilization has an analgesic effect on LBP. In another study, Nwuga [48] found that in the treatment of back pain, spinal manual therapy especially VOP can cause stimulation of the afferent fibre connected to the large diameter nerves to produce a neuro-physiological effect which causes pain relief. Subsequently, other researchers, including Egwu et al. [46], found that VOP is effective in decreasing pain intensity in and in restoring spinal mobility in people with LBP. A study by Ojoawo et al. [41] also revealed that there was a significant improvement in pain and disability when VOP was used in the management of LBP. From the afore-mentioned studies, it can be concluded that VOP is an effective intervention for the management of pain, disability, and spinal mobility in patients with LBP.

Our study found that TP was not effective on pain in the real-world, while there were limited data to ascertain its effect on disability. TP in this study referred to cryotherapy, soft tissue mobilization, electrotherapy, exercises, traction, lumbar oscillatory rotation technique, sacro-iliac joint manipulation, postural correction, transcutaneous electrical muscle stimulation, electrical muscle stimulation, and the use of a lumbar corset. In the physiotherapy clinic where this study was carried out, TP was frequently used in the management of patients with LBP. The modules that make up TP sessions were usually at the discretion of the clinicians as there were no regimented protocol for management of LBP in the setting of the study.

Recently, evidence from real-world studies is being sought in the management of patients [29, 30]. This current advocacy for RWE is based on the findings that RWE can "effectively" complement the knowledge gained from "traditional" clinical trials, whose well-known limitations makes it difficult to generalize findings to larger, more inclusive populations of patients, providers, and healthcare delivery systems, or settings reflective of actual use in practice [29]. While evidence-based practice (EBP) is the standard of practice in physiotherapy, there are emerging studies on practice-based evidence (PBE). EBP, which is generated from scientific research, integrates the best research evidence with clinical expertise and patient values. On the other hand, PBE, is gained over time by means of practice or experience, it is a range of treatment approaches and supports that are derived from, and supportive of, the positive culture of the local society and traditions. Both evidence-based practice and practice-based evidence represent two differing orientations to what is viewed as effective and helpful aspects within specific parameters with ultimately the same goal, which is improving the lives of those served [49]. Thus, the interest in RWE is aimed at complementing the knowledge gained from "traditional" clinical trials [29].

The current study was aimed at determining the RWE for VOP in the management of patients with LBP. The setting where this study was carried out had positive inclination for the use of VOP. The reason may not be unconnected with the fact that the procedure originated from the setting, as well as, having academic faculties who are trained in the art and also train their students. The 59% frequency of use was considered high enough to justify an inquiry into evidence of this practice outside of the typical evidence from RCTs. From the results of our study, VOP is an effective intervention in the real-world for management of pain compared with TP. However, at week four, both interventions were comparable in their mean pain reduction, but at week eight VOP was more effective that TP for the management of pain. There were limited data on disability, and as a result the effects on disability could not be ascertained. In the absence of related studies, the findings from this study can serve as preliminary evidence on the use of VOP specifically and the use of spinal manipulation in general.

It is noteworthy that VOP was mostly used in combination with cryotherapy in this study. The use of VOP and cryotherapy has a long history, as well as, justification for the practice. The use of ice has been advocated following VOP as a means of reducing post treatment pain and muscle soreness that accompanies spinal manipulation. Similar practice is also observed in some other forms of spinal manipulation where ice is used to douse tissue tension and to reduce treatment pain [50]. This may be due to the fact that spinal mobilization or manipulation is often accompanied with post treatment pain and muscle soreness, which physical therapists often manage with cryotherapy. Cryotherapy is used to decrease the local body temperature for therapeutic purposes [50, 51]. Also, the results of the current study showed that VOP was significantly associated with the Lumbar Oscillatory Rotation Technique (LORT). It is a form of manual therapy commonly used for relieving unilateral signs and symptoms and restoring the pain free range of motion [52, 53]. However, clinicians in the study setting combined other forms of therapies with VOP, such as soft tissue mobilization, exercises, electrotherapy, and sacroiliac joint manipulation. While none of these interventions were significantly associated with VOP use, however, transcutaneous electrical nerve stimulation had the least use. It may be as a result of lack or limited availability of the modality in the study setting. Thus, combining VOP with other interventions makes it difficult to isolate the effect of VOP directly. However, potential confounders, such as age and pain duration, show no significant effect on the outcomes.

The findings from the present study showed that there was significant difference in the costs of patients treated with VOP when compared with those that were treated with TP. The data showed that patients treated with VOP incurred more costs than those treated with TP. This is supported by a study [54] which revealed that manipulative treatments are more expensive than other treatments (apart from surgery) and not more helpful in improving patient outcomes. Although, this is contrary to the conclusion of a study carried

out by Williams et al. [55] which revealed that osteopathic manipulative treatment may reduce costs for the management of acute LBP; however, it was further stated that more research in a prospective study would be needed. Higher costs of VOP could be due cost of the physiotherapist's time, cost of transportation, and caregivers fee and productivity loss due to the clinical visit. Whilst TP may be self-administered (e.g. cryotherapy) and could save costs in terms of staff time, the cost of transportation to visit a physiotherapist, it can be implied that the development of self-administered physiotherapy modalities, such as tele-rehabilitation to improve patient outcomes and reduce the costs of physiotherapy interventions, should be explored.

Strengths and limitations of this study

This study is the first to examine the real-world effectiveness of VOP in the management of patients with LBP in Nigeria. It provided insight into real-world effectiveness and costs of VOP. The data for this study were extracted from one physiotherapy facility which may limit generalizing the study to the entire population. The choice of treatment was not at random and thus we cannot rule out known and unknown confounding factors in the observed findings. Another limitation of the study is that substantial numbers of patients received additional treatment(s) in combination with VOP, which makes it difficult to isolate the effect of VOP directly. Also, we could not ascertain the competency of the physiotherapists who administered VOP.

Conclusions

Vertical oscillatory pressure is an effective intervention compared with TP for LBP in 'real world'. VOP is more effective compared to TP on its effect on pain over time but comparable on disability. The costs of delivering VOP was high compared to TP in real-world terms. The findings of this study may inform clinical decisions to improve the health outcomes of patients with LBP. It is recommended that policy makers should adopt the use of RWE studies to inform healthcare decisions. Future studies are required to examine the incremental cost-effectiveness of the interventions.

Disclosure statement

No author has any financial interest or received any financial benefit from this research.

Conflict of interest

Authors state no conflict of interest.

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