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OSTEOPOROTIC SPINE FRACTURES TREATED WITH KYPHOPLASTY OR VERTEBROPLASTY: A META-ANALYSIS

FRATURAS OSTEOPORÓTICAS DA COLUNA TRATADOS COM CIFOPLASTIA OU VERTEBROPLASTIA: UMA METANÁLISE

FRACTURAS OSTEOPORÓTICAS DE LA COLUMNA VERTEBRAL TRATADAS CON CIFOPLASTÍA O VERTEBROPLASTÍA: UN METAANÁLISIS

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ABSTRACT

Kyphoplasty (KP) and vertebroplasty (VP) are both widely adopted treatments for patients with osteoporotic vertebral fractures (OVF), however, which of these techniques is more effective has not yet been established. We performed a systematic review of articles, followed by meta-analysis, in an attempt to establish the differences between KP and VP. Initially, 187 articles were obtained, 20 of which were systematically reviewed and submitted to meta-analysis. Thus, 2,226 patients comprised the universe of the present article, 1202 of whom underwent KP and 1024 of whom underwent VP. The statistically significant results observed included lower mean bone cement leakage (ml) in the group submitted to kyphoplasty, with OR: 1.50 [CI95%: 1.16 - 1.95], p <0.05; shorter mean surgical time (minutes), 0.45 [CI90% 0.08 - 0.82], p <0.1, for the group submitted to VP as compared to the KP group; and a lower mean postoperative Oswestry Disability Index score in the KP group, OR: -0.14 [CI95%: -0.28 - 0.01], p <0.05. KP was more effective in improving physical function and had a lower frequency of cement leakage when compared to VP, although it requires longer surgical time. ***Level of evidence III; Systematic review of level III studies.***

Keywords: Spinal Fractures; Osteoporotic Fractures; Vertebroplasty; Kyphoplasty; Meta-Analysis.

RESUMO

Tanto a cifoplastia (KP) quanto a vertebroplastia (VP) são tratamentos bastante adotados para pacientes com fratura vertebral osteoporótica (FVO), no entanto, ainda não foi estabelecido qual destas é a técnica de maior eficácia. Realizamos uma revisão sistemática de artigos, seguida de metanálise, na tentativa de estabelecer as diferenças entre KP e VP. Foram obtidos inicialmente 187 artigos, sendo que destes, 20 foram revisados sistematicamente e submetidos à metanálise. Assim, 2226 pacientes compuseram o universo do presente artigo, sendo 1202 destes submetidos à KP e 1024 à VP. Entre os resultados estatisticamente significativos, foi observado um menor extravasamento médio de cimento ósseo (ml) no grupo submetido à cifoplastia, OR: 1,50 [IC 95%: 1,16 - 1,95], p < 0,05; o tempo médio de operação (minutos) 0,45 [IC 90%: 0,08 - 0,82], p < 0,1, na comparação entre KP e VP é menor no grupo submetido à vertebroplastia e no pós-cirúrgico, o Índice Médio de Incapacidade de Oswestry foi menor no grupo KP OR: -0,14 [IC 95% -0,28 - 0,01], p < 0,05. A KP foi mais eficaz na melhora da função física e menor frequência de extravasamento de cimento quando comparada à VP embora demande maior tempo cirúrgico. ***Nível de evidência III; Revisão sistemática de estudos de nível III.***

Descritores: *Fraturas da Coluna Vertebral; Fraturas por Osteoporose; Vertebroplastia; Cifoplastia; Metanálise.*

RESUMEN

Tanto la cifoplastía (KP) como la vertebroplastía (VP) son tratamientos ampliamente adoptados en pacientes con fractura vertebral osteoporótica (FVO), sin embargo, aún no se ha establecido cuál de ellas es la técnica más eficaz. Se realizó una revisión sistemática de artículos, seguida de un metaanálisis, en un intento de establecer las diferencias entre KP y VP. Inicialmente se obtuvieron 187 artículos, de los cuales 20 fueron revisados sistemáticamente y sometidos a un metaanálisis. Así, 2226 pacientes constituyeron el universo del presente artículo, 1202 de ellos sometidos a KP y 1024 a VP. Entre los resultados estadísticamente significativos, se observó una menor extravasación media de cemento óseo (ml) en el grupo sometido a cifoplastía, OR: 1,50 [IC 95%: 1,16 - 1,95], p <0,05; el tiempo medio de intervención (minutos) 0,45 [IC 90% 0,08 – 0,82], p <0,1, en la comparación entre KP y VP es menor en el grupo sometido a vertebroplastía y en el posquirúrgico, el Índice de Discapacidad de Oswestry promedio fue menor en el grupo KP OR: -0,14 [IC 95 % CI -0,28 - 0,01], p <0,05. La KP fue más eficaz en la mejora de la función física y con menor frecuencia de extravasación de cemento en comparación con la VP, aunque requiere un tiempo quirúrgico más prolongado. ***Nivel de evidencia III; Revisión sistemática de estudios de nivel III****.*

Descriptores: *Fracturas de la Columna Vertebral; Fracturas Osteoporóticas; Vertebroplastia; Cifoplastia; Metaanálisis.*

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INTRODUCTION

Osteoporosis is an issue of global importance.[1] Among the main complications are osteoporotic vertebral fractures (OVF)[2] with a reported incidence of 117 cases per 100,000 inhabitants, or approximately 1.4 million patients annually.[3] Unlike other types of osteoporotic fractures, OVFs are generally not associated with trauma.[4]

The incidence of fractures due to fragility, osteoporosis, or failure of the vertebrae increases with age. In cases of vertebral fractures due to low-energy trauma, osteoporosis should be suspected and investigated.[5]

OVFs are associated with a significant worsening of patient morbidity and mortality. Over time, patients with OVFs can suffer from chronic pain, reduced quality of life and functionality, low self-esteem, a risk of other fragility fractures, spinal cord compression, and changes in lung function.[6,7] Regarding mortality, an increase of 32%, adjusted for age, has been reported for patients with OVFs.[8]

In the past, non-surgical therapy was considered the gold standard treatment for osteoporotic vertebral compression fractures (OVFs). Currently, minimally invasive techniques, such as percutaneous vertebroplasty (VP) and balloon kyphoplasty (KP), are widely used for treatment of painful OVFs.[9]

After vertebral fragility fractures, the risk of new fractures is high and secondary preventative measures should be taken, the best currently being drug treatment for osteoporosis.[10]

The treatment of osteoporotic fractures varies according to the severity of the condition. Many cases can be treated through non-surgical methods focused on pain control and prevention of deformities. However, in cases where the spinal canal is compromised or there is neurological deficit the treatment will require spinal cord decompression and surgical instrumentation.[11] Among spinal cementation procedures, vertebroplasty and balloon kyphoplasty has been shown to be more effective.[12]

Vertebroplasty was first described to treat aggressive vertebral hemangiomas of the lumbar spine.[13] Bone cement is injected into the vertebra using a transpedicular approach, which helps to stabilize the vertebral fracture, improving strength and stability. In balloon kyphoplasty, a cavity is created in the vertebra using an inflatable balloon, reducing injection pressure and restoring vertebral height.[4]

Given the above, the objective of this meta-analytic review is to compare the effects of kyphoplasty and vertebroplasty in patients with osteoporotic spine fractures, evaluating surgical time, the volume of bone cement leakage, and the mean Oswestry Disability Index score between the two cementation techniques.

METHODS

Study design

In January 2020, a thorough systematic search of the literature was performed on the PubMed, EMBASE, and Cochrane online scientific journal databases for original English-language publications, using Medical Subject Headings (MeSH) and general subjects headings. The search terms were “spinal fractures”, “kyphoplasty”, “vertebroplasty”, and “osteoporotic fractures”. The search was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[14]

Inclusion criteria

The inclusion criteria were original studies that comparatively investigated patients with OVF who underwent vertebroplasty or kyphoplasty and that analyzed the following variables: surgical time, bone cement leakage, and the Oswestry disability index score. Studies including neoplastic vertebral fractures or patients without osteoporosis were excluded. There were no exclusions due to population size, patient age, study design, or follow-up period.

Data collection procedure

The clinical scenario was structured based on PICO components: P (population), I (intervention), C (comparison), O (outcome). P – Osteoporotic vertebral fracture, I – Kyphoplasty, C – Vertebroplasty, O – Effectiveness and adverse events. The search strategy for articles to make up the sample used the PubMed-MEDLINE, EMBASE, and Cochrane scientific databases. A manual search of the references of the reviews (narrative or systematic), as well as of the selected studies, was conducted. In all, 187 articles were retrieved from the three databases. Thirty-six of these were selected based on title and abstract. After analyzing the full texts and abstracts, 20 (twenty) studies were included for evaluation. Most of the remaining articles were excluded because they described RCTs that did not compare vertebroplasty with kyphoplasty. The database search strategies were applied blindly and independently by two investigators, rigorously following the inclusion and exclusion criteria so that only potentially relevant articles were selected. The selected articles consisted of randomized clinical trials and prospective and retrospective cohort studies available in English.

The strength of evidence of the RCTs was defined taking the study design and the corresponding risks of bias (randomization, blinding, loss, prognostic characteristics, results, intention-to-treat analysis, sample size calculation), analysis results (magnitude and accuracy), relevance, and applicability (Oxford/GRADE) into account.[15]

Data analysis

The two reviewers independently entered the data into RevMan 5.3 software. Dichotomous outcomes were expressed as odds ratios (OR) and the mean weighted difference or the standard mean differences was used for continuous outcomes, both with confidence intervals of 90% (CI90%) and 95% (CI95%). Heterogeneity was tested using the chi-squared test and the I^2 test. A fixed effects model was chosen when there was no statistical evidence of heterogeneity (I^2<50%) and a random effects model was adopted if significant heterogeneity was found. If heterogeneity was found, we checked the population, the treatment, the results, and the study methodologies to determine the source. If it could not be synthesized quantitatively or the event rate was too low to measure, we conducted a qualitative assessment, eliminating some of the studies for sensitivity analysis and creating funnel charts to evaluate the bias.

RESULTS

Eligible studies

The flowchart (Figure 1) shows the results retrieved and the study selection process. In accordance with the predetermined strategies,

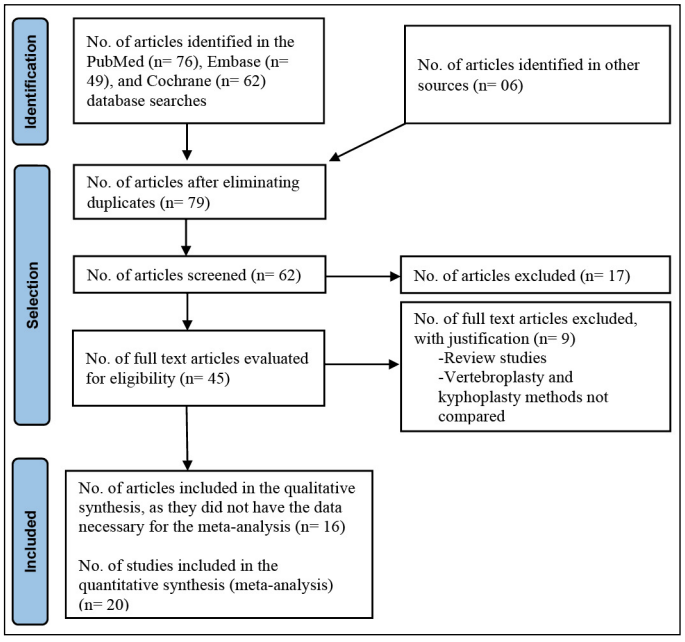

Figure 1. Flowchart showing the study selection process and the results retrieved.

76, 49, and 62 relevant studies were selected from the databases of the PubMed-MEDLINE, EMBASE, and Cochrane libraries, respectively. After removing duplicate articles, ineligible studies, and studies that did not include a VP x KP analysis, a total of 20 eligible studies were selected for the meta-analysis. Of these, 4 were randomized clinical trials, 6 were prospective cohort studies, and 10 were retrospective cohort studies, involving a total of 2226 patients, 1202 of whom underwent KP and 1024 of whom underwent VP. The characteristics of each study are described in Table 1.[16-35]

The meta-analysis results presented a statistically significant effect between KP and VP in the percentage of bone cement leakage (ml), with an odds ratio of 1.50 [CI95% 1.16 – 1.95], $p < 0.05$, with a large effect size. There was low heterogeneity between the studies, with low variability ($I^2 = 37\%$) (Figure 2). Mean bone cement leakage (ml) was significantly greater in the group that underwent VP ($p<0.05$).

In addition, the meta-analysis results also presented a statistically significant effect in terms of the surgical procedure time (minutes), with a difference in the standardized means: 0.45 [CI90% 0.08 – 0.82], $p < 0.1$, between KP and VP, with a small magnitude of effect. There was heterogeneity between the studies, with high variability ($I^2 = 91\%$), demonstrating a shorter duration for VP (Figure 3).

The results obtained were also statistically significant in terms of the Oswestry Disability Index scores in postoperative follow-up, with a difference between the standardized means: -0.14 [CI95% -0.28 – 0.01), $p < 0.05$ in the KP x VP relationship. There was heterogeneity among the studies with non-significant ($p = 0.35$) low variability ($I^2 = 10\%$) (Figure 4). The mean postoperative Oswestry Disability Index score was lower in the group that underwent kyphoplasty, with a significant difference ($p < 0.05$).

DISCUSSION

Biomechanical studies have demonstrated that a minimum volume of cement or volume fraction of the cemented vertebral

Table 1. Summary table of the articles included in the systematic meta-analytic review that report the effects of treatment with kyphoplasty and vertebroplasty in patients with osteoporotic spine fractures.

Article	Country	Publication year	Design	Population		Age (years)		Follow-up (months)
				KP	VP	KP	VP	
Bozkurt et al.[16]	Turkey	2014	Retrospective	200	96	57.5	57	40
Cheng et al.[17]	China	2019	Retrospective	172	96	68.4±10.3	66.7±9.8	12
Dohm et al.[18]	USA	2014	RCT	191	190	75.6		24
Dong et al.[19]	China	2013	Retrospective	51	35	69.8	70.5	21.3
Ee et al.[20]	England	2012	Retrospective	97	148	75	77	24
Endres et al.[21]	Germany	2011	RCT	20	21	63.3	71.3	5.8
Folman et al.[22]	Israel	2011	Prospective	31	14	70.7	75.6	12
Frankel et al.[23]	USA	2007	Retrospective	17	29	70	72	3.5
Gan et al.[24]	China	2014	Retrospective	41	38	69.1	67.1	43.5/41.4
Grohs et al.[25]	Austria	2005	Prospective	28	23	70	70	24
Hiwatashi et al.[26]	Japan	2008	Retrospective	40	66	75	77	NR
Kong et al.[27]	China	2014	Retrospective	29	24	71.9	70.5	12
Kumar et al.[28]	Canada	2009	Prospective	24	28	73	78	42.3/42.2
Li et al.[29]	China	2012	Prospective	45	40	68.5	67.1	12
Liu et al.[30]	Taiwan	2015	RCT	50	50	72.3	74.3	72
Liu JT et al.[31]	Taiwan	2009	RCT	50	50	72.3	74.3	72
Movrin et al.[32]	Slovenia	2010	Prospective	46	27	67.8	72.9	1
Omidi-Kashani[33]	Iran	2013	Prospective	29	28	72.1/72.4	6m	13
Yu H et al.[34]	China	2020	Retrospective	28	14	71.56	74.47	10 to 42
Yu W et al.[35]	China	2016	Retrospective	20	48	74.6	72.9	2

NR = not reported, RCT = randomized clinical trial. The follow-up period is expressed in months, unless otherwise indicated.

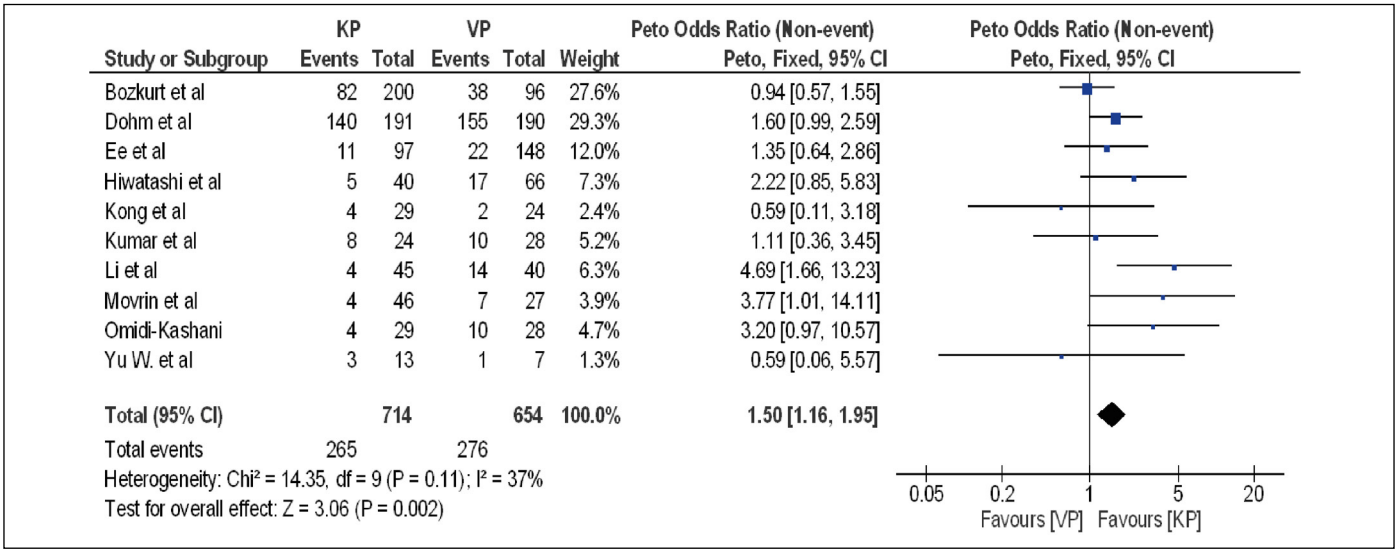

Figure 2. Meta-analysis graph (forest plot) reporting the effects of treatment with kyphoplasty and vertebroplasty in patients with osteoporotic spinal fractures in terms of bone cement leakage (mL)

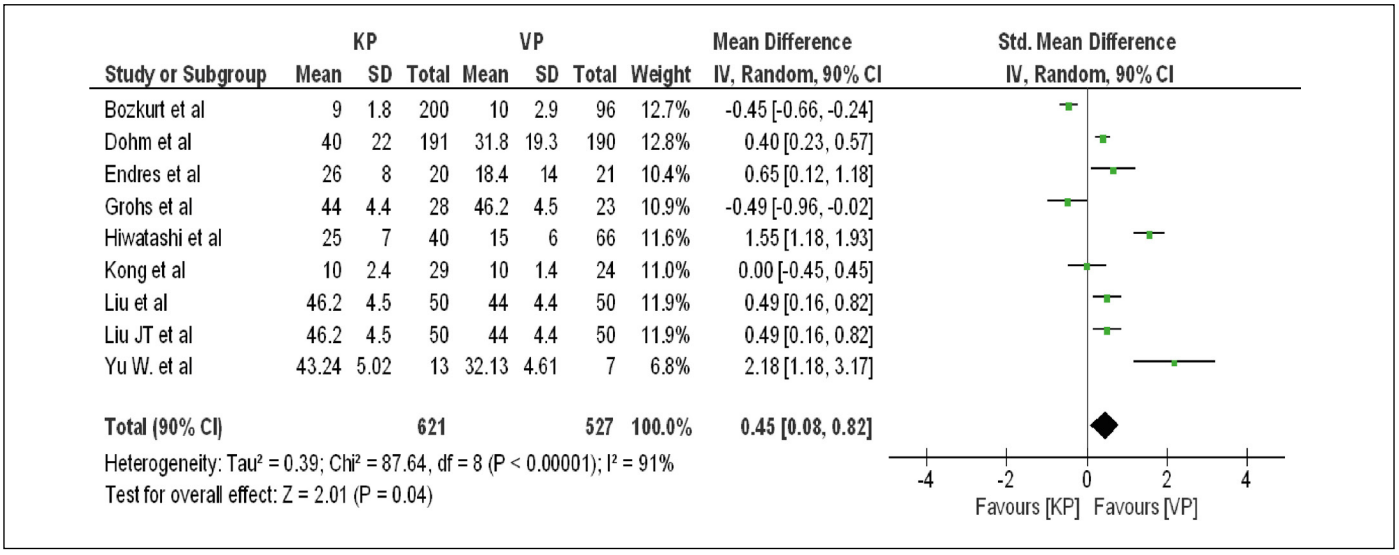

Figure 3. Meta-analysis graph (forest plot) reporting the effects of treatment with kyphoplasty and vertebroplasty in patients with osteoporotic spinal fractures in terms of surgical time (minutes).

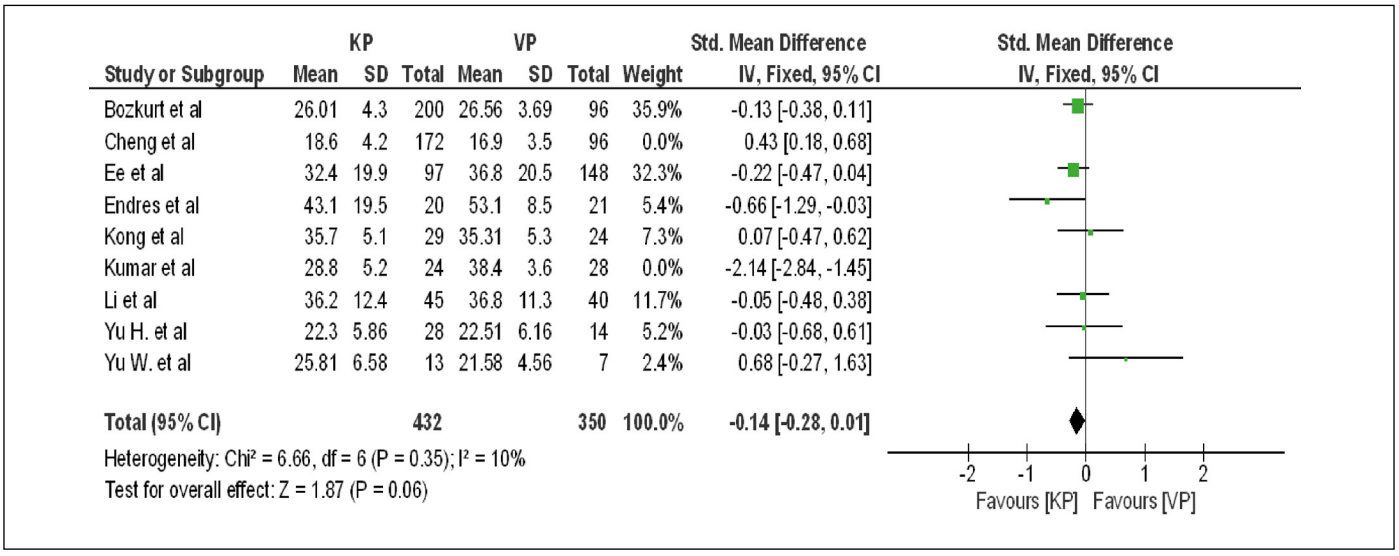

Figure 4. Meta-analysis graph (forest plot), with heterogeneity correction, reporting the effects of treatment with kyphoplasty and vertebroplasty in patients with osteoporotic spinal fractures in terms of the Oswestry Disability Index

body is necessary to restore the mechanical properties of the fractured vertebra.[36]

As in our study, Patel et al.,[37] attributed a greater risk of cement leakage to VP as compared to KP. Cement leakage into the surrounding tissue, intradiscally, and into the vertebral canal is the main complication associated with VP. Although rare, pulmonary embolism and spinal stenosis can be related to this event.

While KP has a lower risk of cement leakage, it is associated with longer surgical time, and it may be uncomfortable and intolerable for the patient to remain in the same position for an extended period of time. This longer surgical time is also associated with greater exposure to fluoroscopy.[38]

In the evaluation of postoperative improvement of patient disability, pain, and quality of life by means of the Oswestry Index, KP proved to be able to achieve positive results.[39] In the comparison between KP and VP, Ding et al.[40] reported better disability improvement results in the group submitted to KP, just as in our study. However, in the literature, comparative studies of the two techniques are limited and the results inconclusive as regards improvement of disability.[41]

The ideal meta-analysis would include only RCTs with little heterogeneity. However, RCTs are rare for surgical procedures.

CONCLUSION

In conclusion, we identified that the KP procedure involves less cement leakage and a lower mean Oswestry Disability Index score, but VP surgery requires less time. Additional RCTs are necessary to confirm these conclusions and select the best surgical procedure for patients with OVFs.

All authors declare no potential conflict of interest related to this article.

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