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Comparison of radiofrequency kyphoplasty (RFK) and balloon kyphoplasty (BKP) in the treatment of vertebral compression fractures

A meta-analysis

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Abstract

Background: Balloon kyphoplasty (BKP) is a widely adopted minimally invasive treatment for vertebral compression fractures (VCFs), but leakage of cement is a main complication of BKP. A novel vertebral augmentation technique radiofrequency kyphoplasty (RFK) with high viscosity cement was developed in 2009. Here, we aim to evaluate whether RFK can relieve symptoms efficiently and reduce cement leakage.

Methods: A literature search was performed using Pubmed, Embase, and Cochrane CENTRAL until September 30, 2016. Both randomized controlled trial (RCT) and non-RCT studies comparing RFK and BKP were included. The main outcomes included pain relief (VAS), functionality improvement (ODI), operation time, reduction of deformity (vertebral height and kyphosis angle), and incidence of cement leakage. The origin of heterogeneity was further explored by subgroup stratification.

Results: A total of 6 studies involving 833 patients with VCFs were included. The reduction of VAS score in the RFK group was 3.96 points more than that in the BKP group (P = .0007) postoperatively, and the improvement persisted until 12 months after the surgery (P < .00001). The operation time was shorter in RFK group than that in BKP group (P = .01). The increase of anterior vertebral height shortly after the operation was 0.53 mm greater in RFK group (P = .01). The decrease of kyphotic angle after RFK was 0.63° and 0.92° greater than that after BKP, both immediately and 6 months after operation (P = .002 and P < .00001, respectively). There was no significant difference between the incidence of cement leakage after RFK and BKP (P = .06). Further subgroup analysis stratified by study design indicated that the incidence of leakage decreased 15% in RFK than BPK (P < .00001) in non-RCT subgroup, but RFK and BKP treatments were equivalent in the RCT studies (P = .86).

Conclusion: RFK appears to be more effective and safer than BKP in the present meta-analysis. The incidence of cement leakage diverges in RCT and non-RCT studies, so large-sample multicentered RCT studies are required to validate this new surgery system.

Abbreviations: BKP = balloon kyphoplasty, CI = confidence interval, ODI = Oswestry disability index, RCT = randomized controlled trial, RFK = radiofrequency kyphoplasty, RR = risk ratio, VAS = visual analogue scale, VCF = vertebral compression fracture.

Keywords: balloon kyphoplasty, meta-analysis, radiofrequency kyphoplasty, vertebral compression fractures

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1. Introduction

Vertebral compression fracture (VCF) is a growing health problem worldwide, associated with high risks of morbidity and mortality. It occurs in 20% of people older than 70 years and 16% of women postmenopausal.^[1] VCFs usually involve thorax and lumbar sections, which can arise with minor injury or no injury when the patients suffer from osteoporosis, bone tuberculosis, or bone tumor invasion. It can cause pain, impair mobility, and diminish quality of life. Conservative management cannot reverse the kyphotic deformity resulting from the height decrease of the anterior vertebrae.

Vertebroplasty (VP) has been used for the treatment of VCF since 1984,^[2] and after that it become an internationally recognized method, which can relieve pain immediately, stabilize vertebral bodies, and reduce the risks of bed rest related complications. Later kyphoplasty (KP) was introduced to treat VCF,^[3] and both of them were considered safe and effective to treat painful VCFs irresponsive to conventional treatments.^[4,5]

Balloon kyphoplasty (BKP) place catheters with inflatable bone tamps into the affected vertebral body, and the balloon inflation pushes the endplates apart, to relieve pain, partly restore height and correct kyphotic deformity.^[6,7] The problems with BKP are the accidental loss of cement and the risk of cement leakage. An

innovative procedure radiofrequency kyphoplasty (RFK) that use radiofrequencies to activate highly viscous cement has been available since 2009. There are only limited studies comparing the complications such as cement leakage between RFK and BKP. No randomized controlled trials (RCTs) were published until 2016.^[8,9]

We performed this meta-analysis to assess treatment of RFK, by comparing the effectiveness of relieving pain and regaining mobility, assess the radiological correction, and evaluate the safety between RFK and BK.

2. Methods

This meta-analysis followed PRISM statement standard. The protocol was registered in the PROSPERO database (registration number: CRD42016051497. http://www.crd.york.ac.uk/pros pero). Since the analyses were based on previous published studies, no ethical approval and patient consent were required.

2.1. Search strategy

In order to find all the relevant published studies, articles related to radiofrequency and vertebroplasty were identified through computerized searches using the keywords as follows: (radiofrequency OR rfk OR "rf tva" OR stabilit) AND (kyphoplasty OR vertebroplasty). Two reviewers independently searched the studies published in all languages via 3 databases, including Pubmed, Embase, and Cochrane CENTRAL up to September 30, 2016. The discrepancies were discussed to achieve consensus. In addition, we hand-searched the reference lists of the achieved articles to include all available studies.

2.2. Inclusion and exclusion criteria

Studies that met the following criteria were enrolled in this analysis: they were comparative studies, including RCTs and non-RCTs; the patients suffered from VCF of traumatic, osteoporotic, or malignant etiologies; thorax and lumbar fractures; they compared FKP versus BKP; and they reported one of the following outcome parameters: visual analog scale (VAS), Oswestry disability index (ODI), operation time, vertebral body height, kyphotic angle, and cement leakage.

The exclusion criteria were as follows: they were single-arm trials; no relevant data could be extracted; and when the same research group investigated a similar population, only the study with the largest sample size was adopted and the others were excluded from the analysis.

2.3. Data extraction and quality assessment

Two reviewers extracted data from every study independently, and the disagreements were resolved by discussion. The common characteristics of study and the outcome parameters were extracted. The common characteristics included: name of the first author; publication year; country; study design; case number (n); age; gender; and indication. The clinical outcomes included VAS, ODI, and operation time. Radiographic outcomes included the vertebral body height and kyphotic angle. Complication outcome included bone cement leakage.

According to the method guidelines for systematic reviews in Cochrane Back Review Group, a 12-item scale was adopted to evaluate the quality of studies.^[10] Two reviewers independently evaluated every study, and they discussed to resolve the discord.

Six aspects including the randomization, allocation concealment, blinding of participants and personnel, incomplete outcome data, selective reporting, and others were assessed by 12 items, with score as low risk of bias, unclear risk of bias, or high risk of bias.

2.4. Statistical analyses

Review Manager Software (RevMan Version 5.2) was used for the meta-analysis. The continuous outcomes were assessed by calculating mean difference (MD) and a 95% confidence interval (CI) among the pooled data, and the statistical significance was calculated by Z test. For dichotomous outcomes, the risk ratios (RRs) and 95% CI were assessed. A fixed-effect model (FEM) was applied to calculate parameters of the data pool when no serious heterogeneity was found (*P* value \geq .1 by the Q test), and the calculation was performed by a random-effect model (REM) if the heterogeneity is serious.^[11] Subgroup analysis by study design was executed to define the possible origin of the severe heterogeneity. Publication bias was evaluated by examining funnel plots and assessing the asymmetry of funnel plot. *P* < .05 was considered to be statistically significant.

3. Results

3.1. Search results

As seen in Fig. 1, the literature review identified 100 records in PubMed, 311 records from Embase, and 10 records from Cochrane CENTRAL that met the search criteria. After duplication removal and review of title and abstract, 18 full-texts were achieved. Later, 8 studies were extracted because the similar investigated population,^[12–19] 3 were extracted because they studied the vertebral samples, not clinical studies,^[20–22] and 1 was extracted because the fracture located in sacrum.^[23] At last, 6 studies with 833 subjects were included in quantitative synthesis.^[8,9,24–27]

3.2. Characteristics of the included studies and quality assessment

The characteristics of the included studies are listed in Table 1. There were 5 studies from Germany^[8,9,24,26,27] and 1 study from USA.^[25] The extracted studies included 2 RCTs,^[9,24] 1 prospective cohort studies,^[26] and 3 retrospective cohort studies.^[8,25,27] Five studies were published in English while 1 was in German.^[26] The majority of the included patients suffered from osteoporotic VCF, and meanwhile malignant and traumatic VCF were involved in a part of the studies. There was no significant difference in age and gender between the 2 groups (P > .05).

Figures 2 and 3 summarized the methodological quality of the included studies. Two RCT studies^[9,24] reported adequate randomization, but the allocation concealment and blinding during study were unclear, and the outcomes were not reported satisfactorily enough. The rest 4 studies^[8,25–27] were not RCTs, and the randomization, concealment, blind, and outcome were of high risk of bias. All studies offered similar baseline and cointerventions.

3.3. Outcome analysis

3.3.1. Clinical outcomes. Four studies reported the reduction in the intensity of pain with VAS scores^[8,9,26,27] (Fig. 4). FEM analysis showed that, after surgery, the reduction of VAS score in the RFK group was 3.96 points more than that in the BKP group



Figure 1. Flow chart of study selection for the comparison of RFK and BKP. BKP=balloon kyphoplasty, RFK=radiofrequency kyphoplasty.

(95% CI, 1.67–6.24; P=.0007). Twelve months after the surgery, a notable additional improvement was found in the RFK group compared to the BKP group (95% CI, 8.96–13.91; P < .00001). There was no significant heterogeneity among the studies (P=.44 and .81 for the I^2 test).

Only 2 studies reported the improvement of functional impairment with ODI scores^[8,26] (Fig. 5). The pooled analysis showed that, ODI improved more in the RFK group immediately postoperatively (P=.04), but there were no

significant differences in ODI improvement between the 2 groups 12 months after surgery (P=.60). REM analysis was performed because of the significant heterogeneity (P<.0001 for the I^2 test).

Three studies reported the operation time of both RFK and BKP^[8,9,26] (Fig. 6). REM analysis was adopted because of the significant heterogeneity (P < .00001 for the I^2 test) and showed that on average, the operation time of RFK was 15.45 minutes less than that of BKP (95% CI, 3.15–27.75; P = .01).

Table 1 Characteristics of the included studies.

	Public			Case number (n)		Mean age, y		Gender (M/F)			
Study	year	Country	Study design	BKP	RFK	BKP	RFK	BKP	RFK	Indication	
Licht ^[27]	2010	Germany	Retrospective	137	24	NA	NA	NA	NA	VCF	
Pflugmacher ^[26]	2012	Germany	Prospective	114	114	65.2 ± 9	70.1±9	48/66	41/73	Osteoporotic VCF	
Georgy ^[25]	2013	USA	Retrospective	35	37	80.8	74	7/28	14/31	Osteoporotic/malignant VCF	
Riesner ^[24]	2016	Germany	RCT	100 for	2 groups	78.5 for	2 groups	24/76 for	2 groups	Traumatic/osteoporotic/malignant VCF	
Petersen ^[9]	2016	Germany	RCT	44	36	81.8±8	81.7 ± 6	9/35	12/24	Osteoporotic/malignant VCF	
Bornemann ^[8]	2016	Germany	Retrospective	96	96	67.9 ± 7.7	69.6 ± 9.4	37/59	39/57	Osteoporotic VCF	

BKP=balloon kyphoplasty, NA=not available, RCT=randomized controlled trial, RFK=radiofrequency kyphoplasty, VCF=vertebral compression fracture.





3.3.2. Radiographic outcomes. Only 2 studies reported the height restoration of vertebra, anterior, or middle^[8,26] (Fig. 7). REM analysis showed that the increase of anterior vertebral height shortly after the operation was 0.53 mm greater in RFK group compared with that in BKP group (95% CI, 0.11–0.96; P=.01). However, the difference disappeared 6 months after surgery (P=.12). REM analysis showed that the increase of middle vertebral height did not differ between the 2 groups, both shortly and 6 months after operation (P=1.00 and .28).

Three studies reported the improvement of kyphotic angle, expressed as decrease of kyphotic angle^[8,9,26] (Fig. 8). FEM analysis was adopted because no significant heterogeneity was found (P=.47 for the I^2 test), which showed that immediately after operation, decrease of kyphotic angle was 0.63° more than that of BKP (95% CI, 0.24–1.02; P=.002). Six months after operation, the superiority remained, with 0.92° more improvement of kyphotic angle (95% CI, 0.52–1.32; P<.00001).



Figure 3. Quality assessment of every included study.







Figure 5. Forest plot of meta-analysis of the association between RFK/BKP and functional impairment. BKP=balloon kyphoplasty, RFK=radiofrequency kyphoplasty.



Figure 6. Forest plot of meta-analysis of the association between RFK/BKP and operating time. BKP=balloon kyphoplasty, RFK=radiofrequency kyphoplasty.

	Experim	nental (F	RFK)	Cont	rol (Bl	KP)		Mean Difference		Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV. Fixed, 95% Cl	Year	IV. Fixed, 95% CI
2.3.1 anterior postope	eration									
Pflugmacher 2012	3.2	2	114	2.6	2	114	66.9%	0.60 [0.08, 1.12]	2012	
Bornemann 2016	2.9	2.4	96	2.5	2.8	96	33.1%	0.40 [-0.34, 1.14]	2016	
Subtotal (95% CI)			210			210	100.0%	0.53 [0.11, 0.96]		◆
Heterogeneity: Chi ² = (0.19, df = 1	(P = 0.6	66); l ² = 1	0%						
Test for overall effect:	Z = 2.46 (P	= 0.01)								
3 2 anterior 6 month	he after on	oration								
Oflugmacher 2012	27	2	114	22	2	114	65 1%	0 40 [-0 12 0 02]	2012	+
Bornemann 2016	2.1	23	96	2.3	27	06	34 0%	0.20[-0.12, 0.92]	2012	
Subtotal (95% CI)	2.0	2.5	210	2.5	2.1	210	100.0%	0.33 [-0.09 0.75]	2010	
Jotorogonoity: Chi ² = (20 df - 1	(D - 0.6	C). 12 -	00/		210	100.070	0.00[-0.00, 0.10]		
Telefogeneity. Chir - t	7 = 1.54 (D)	-0.12), I ² – (0 70						
rest for overall effect.	Z = 1.54 (P	= 0.12)								
2.3.3 mid postoperati	on									
Pflugmacher 2012	3.1	2	114	3.1	2	114	62.2%	0.00 [-0.52, 0.52]	2012	
Bornemann 2016	2.7	2.2	96	2.7	2.5	96	37.8%	0.00 [-0.67, 0.67]	2016	
Subtotal (95% CI)			210			210	100.0%	0.00 [-0.41, 0.41]		+
Heterogeneity: Chi ² = (0.00, df = 1	(P = 1.0)	$(00); ^2 = 0$	0%						
Test for overall effect:	Z = 0.00 (P	= 1.00)								
2.3.4 mid 6 months at	fter operati	ion								
Pflugmacher 2012	2.5	2	114	2.8	2	114	61.1%	-0.30 [-0.82, 0.22]	2012	
Bornemann 2016	2.4	2.2	96	2.5	2.4	96	38.9%	-0.10 [-0.75, 0.55]	2016	
Subtotal (95% CI)	1000		210			210	100.0%	-0.22 [-0.63, 0.18]		-
Heterogeneity: Chi ² = (0.22, df = 1	(P = 0.6)	64); ² = 1	0%						
Test for overall effect:	Z = 1.07 (P	= 0.28)								
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Figure 7. Forest plot of meta-analysis of the association between RFK/BKP and height restoration of vertebra, anterior, or middle. BKP=balloon kyphoplasty, RFK=radiofrequency kyphoplasty.



Figure 8. Forest plot of meta-analysis of the association between RFK/BKP and improvement of kyphotic angle. BKP=balloon kyphoplasty, RFK=radiofrequency kyphoplasty.

3.3.3. Complication outcome. All 6 of the studies reported the cement leakage rate^[8,9,24–27] (Fig. 9). There was significant heterogeneity among the studies (P=.0002 for the I^2 test), so REM analysis was adopted to compare the RR between the 2 groups. The overall pooled results showed that the absolute risk difference (RD) between the groups was 11% in favor of RFK (P=.005). This corresponded to an RR of 1.79 in favor of RFK (95% CI, 0.97–3.32; P=.06).

In order to explore the origin of heterogeneity, subgroup analysis stratified by study design was performed, which showed that the heterogeneity in both RCTs and non-RCTs was mild (P=.43 and .47), while the subgroup difference was severe

(P < .0001). RFK and BKP treatments were equivalent in the RCT studies (95% CI, .78–1.23; P = .86). However, in the non-RCT studies, the absolute RR was reduced by 15% in RFK compared with BPK (P < .00001). All above indicated that the conclusion diverged between RCTs and non-RCTs.

3.4. Publication bias

To assess the potential publication bias funnel plots were applied for every analysis. No significant asymmetry was found by visual inspection of the funnel plots, which suggested that there was no obvious publication bias in this meta-analysis.

	BKP		RFK		Risk Ratio			Risk Ratio		
Study or Subgroup	Events	Total	Events	Total	Weight	M-H. Random, 95% Cl	Year	M-H. Random, 95% CI		
1.13.1 non RCT										
Licht 2010	26	137	3	24	13.2%	1.52 [0.50, 4.62]	2010			
Pflugmacher 2012	31	114	7	114	17.0%	4.43 [2.03, 9.64]	2012			
Georgy 2013	6	35	3	37	11.3%	2.11 [0.57, 7.81]	2013			
Bornemann 2016	23	96	9	96	17.7%	2.56 [1.25, 5.23]	2016			
Subtotal (95% CI)		382		271	59.2%	2.76 [1.76, 4.31]		•		
Total events	86		22							
Heterogeneity: Tau ² =	0.00; Chi ²	= 2.74	, df = 3 (F	9 = 0.43	3); l ² = 0%					
Test for overall effect:	Z = 4.44 (I	P < 0.0	0001)							
1.13.2 RCT										
Riesner 2016	48	79	53	83	22.5%	0.95 [0.75, 1.21]	2016	+		
Petersen 2016	15	44	10	36	18.3%	1.23 [0.63, 2.39]	2016			
Subtotal (95% CI)		123		119	40.8%	0.98 [0.78, 1.23]		•		
Total events	63		63							
Heterogeneity: Tau ² =	0.00; Chi ²	= 0.53	, df = 1 (F	= 0.47	7); l ² = 0%					
Test for overall effect:	Z = 0.18 (I	P = 0.8	6)							
Total (95% CI)		505		390	100.0%	1.79 [0.97, 3.32]		◆		
Total events	149		85							
Heterogeneity: Tau ² =	0.42; Chi ²	= 24.1	6, df = 5 (P = 0.0	0002); l ² =	79%				
Test for overall effect:	Z = 1.87 (I	P = 0.0	6)		6.2					
Test for subgroup diffe	erences: C	$hi^2 = 16$	6.35, df =	1 (P <	0.0001), l ²	= 93.9%		Favours [RFR] Favours [BRP]		

Figure 9. Forest plot of subgroup meta-analysis of the association between RFK/BKP and cement leakage rate. BKP = balloon kyphoplasty, RFK = radiofrequency kyphoplasty.

4. Discussion

RFK was introduced in 2009, which used a unique hydraulic pressure delivery system, StabiliT Vertebral Augmentation System (DFINE, San Jose, CA), in conjunction with an ultrahigh viscosity bone cement. It was expected that this combination could relieve symptoms faster, reduce operation time and cost, and improve safety.^[28] Since this technique has been carried out for only a short time, the evidence of the effect of this technique was quite limited. There are several studies investigating the treatment of RFK in 2016, so we could perform an analysis to compare the results of RFK and other treatments. Considering that BKP is an effective minimally invasive procedure to treat VCF, which can relieve pain and improve quality of life. We took BKP as the control group to investigate the role of RFK on pain relief, deformity correction, and complication reduction.

RFK realized pain relief better than BKP shortly after operation, and this advantage persisted 1 year later. Since pain could destroy the function, affect the movements, and cause plenty of complications, to stop pain promptly is crucial for the treatment of VCFs. RFK works better in this aspect. Meanwhile, RFK could cut down the time of operation. This reduction might decrease the risks of infection and anesthesia, improve the safety of operation.

Our analysis found that the restoration of anterior vertebral height after RFK surpassed that after BKP, but the difference gradually reduced as time goes by. On the other hand, both immediately and 6 months after operation, decrease of kyphotic angle was more significant in RFK group than that of BKP group. Then why RFK could correct the deformity of vertebra better? We know that BKP involved procedures of vertebral expansion, cavity formation, and height retrieval, and this process might deteriorate the surrounding trabecular structures and elevate the risk of refracture.^[21] RFK has an advantage here. It can preserve the noninvolved and structurally sound trabeculae tissues and stabilize the fracture faster and continuously. Meanwhile, highviscosity cement could provide more resistance and fill the canal better compared with low-viscosity cement.^[29] In addition, the steady hydraulic pressure delivery of an ultrahigh viscosity cement is capable of restoring vertebral height by simultaneously creating and filling a cavity within the fractured vertebrae.

In the present analysis, the overall pooled RR of cement leakage was reduced a bit in RFK group compared to BKP group, but no significance was detected. It was widely expected that RFK could decrease the risk of cement leakage, and the reasons were as follows: first, it was demonstrated that viscosity of the injected cement correlated negatively to the risk of leakage, and high sufficiently viscosity could prevent cement leakage complete-ly.^[30,31] Second, the use of StabiliT ER bone cement makes possible a long working time of over 20 minutes.^[28] In that case, the operators have plenty of time for cannula adjustments and multiple intermittent cement deliveries, which could reduce the risk of cement leakage.

However, further subgroup analysis stratified by study design found that in RCTs RFK and BKP treatments were equivalent while in non-RCTs the risk of cement leakage reduced in RFK group. Considering the multiple confounders in non-RCTs, the superiority of RFK could originate from the bias of non-RCT studies. Further better designed RCT studies were required to provide reliable evidences of the treatment of RFK. Meanwhile, because studies with osteoporotic, malignant, and traumatic VCFs were all included in this study, some bias regarding cement leakage and outcome might stem from the heterogeneity of studied populations. If more studies are included in the future study, stratification of operation indications can be performed to exclude the bias originated from existing diseases leading to VCFs.

The primary limitation of the present analysis is the limited number of included studies, that is, 6 studies. Because RFK treatment was started in 2009, so the available information was quite limited. We hope that this analysis could summarize and incorporate the recent data in 2016 to attract more attention and give rise to a new era. The 2nd is the quality of the included studies. Only 2 studies were RCTs and all the others were non-RCTs. In the future, RCT studies will be helpful to evaluate the effects and complications of RFK.

5. Conclusion

RFK appears to be more effective and safer than BKP in the present meta-analysis, with lower incidence of cement leakage. More large-sample multicentered RCT studies are required in future to validate this new surgery system.

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