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Review Article

Efficacy of platelet-rich plasma injection in the treatment of frozen shoulder: A systematic review and meta-analysis

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Abstract.
BACKGROUND: Frozen shoulder (FS) is characterized by progressive shoulder pain and a limited range of motion. Recently, platelet-rich plasma (PRP) injection is a newly developed treatment option for patients with FS and its efficacy needs to be examined.
OBJECTIVE: By conducting a systematic review and meta-analysis, this study attempted to evaluate the efficacy of PRP injection in the treatment of patients with FS.
METHODS: PubMed, EMBASE, Web of Science, Elsevier, The Cochrane Library, WanFang Data and CNKI databases were searched up to May 31, 2020. This study included randomized controlled trials as well as prospective cohort studies. Two reviewers independently screened the title, abstract and full text in order to extract data from qualified studies. The main outcome was pain visual analogue score (VAS) while the secondary outcome was range of motion (ROM) of the shoulder joint that consists of four parts: internal rotation, flexion, external rotation and abduction.
RESULTES: Three randomized controlled trials and one prospective cohort study met the inclusion criteria. Accordingly, a total of 359 cases were analyzed and followed up to 3 months. The control group included corticosteroids (CS), ultrasound therapy, and stellate ganglion block. Compared to other groups, VAS was statistically significant after 1 month and 3 months of treatment (SMD: -0.46, 95% CI: -0.75 to -0.18, $P = 0.002$; $I^2 = 43.2\%$), (SMD: -0.87, 95% CI: -1.23 to -0.50, $P = 0.00$, $I^2 = 61.9\%$). Compared to the control group, only flexion of the patients treated with PRP demonstrated no significant improvement at 1 month, whereas internal rotation, flexion, external rotation and abduction of the shoulder were found to be improved following 3 months of treatment.
CONCLUSIONS: The corresponding findings illustrate that compared to other non-operative treatments, local injection of PRP can effectively improve pain and shoulder motion in patients with FS. However, due to the short follow-up time and limitations regarding the quantity and quality of studies, the above conclusions require further elucidation by performing additional high-quality studies.

Keywords: Corticosteroids, PRP, randomized controlled trial

1. Introduction

Frozen shoulder (FS), which is also referred to as adhesive capsulitis, is characterized by progressive shoulder pain and a limited range of motion [1]. The incidence of FS in the general population is about 2%–5%,

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mainly in the middle-aged and elderly between 40–70 years of age. The incidence of FS in diabetic patients reached as high as 20%. Its etiology is complicated as joint degeneration and chronic strain related [2,3]. The basic pathology involves soft tissue fibrosis of the articular cavity, capsule, ligament and aseptic inflammation [4]. The long-term delay of the disease negatively impacts patients' psychology and aggravates their pain. Currently, non-operative treatment includes e.g. non-steroidal anti-inflammatory drugs, intra-articular injection of CS, suprascapular nerve block, and physical therapy [5–9]. NSAIDs may relieve pain and reduce sleep disturbance, but they do not have a substantial effect on recovery.

Intra-articular injection of CS is still one of the most commonly used methods for the treatment of FS. However, CS injection has been found to be associated with hyperglycemia, which is harmful to articular cartilage, increasing the risk of tendon rupture, local skin depigmentation and subcutaneous tissue atrophy [10]. Although many treatment methods exist, their overall effect is not ideal, and they contain side effects. Therefore, how to improve the curative rate of FS and reduce the side effects of treatment has become a focus of current research.

Platelet-rich plasma (PRP) injection is a new form of treatment, which is a concentrate of PRP obtained by repeated centrifugation of the patients' peripheral blood [11]. PRP contains many components, such as platelet-derived growth factor (PDGF), platelet-derived epidermal growth factor (PDEGF), transforming growth factor β1 (TGF-β1), insulin-like growth factor (IGF), β-fibroblast growth factor (β56 FGF), vascular endothelial growth factor (VEGF), and endothelial growth factor (ECGF) [12–14].

Because of its advantages, PRP injection has been gradually used in the clinical treatment of osteoarthritis, lateral epicondylitis, rotator cuff injury, tendon disease, metatarsal fasciitis and other diseases demonstrating good effects in tissue repair. Systematic reviews have also shown that PRP can effectively treat tendon, ligament, cartilage and muscle injuries [15]. However, some studies confirmed that there was no superior clinical benefit of PRP compared with the control for knee osteoarthritis [39] or achilles tendon rupture [40]. Hall et al. [16] reported the outcomes of PRP in the treatment of rotator cuff repair through shoulder arthroscopy. After two years of follow-up, no related complications occurred, and the pain visual analogue score (VAS) and range of motion (ROM) scores of all patients increased compared with those before the operation. Nevertheless, a systematic review suggested that more studies should be conducted in the future to confirm reliable results due to the low quality of the methodology. Besides, in-depth studies are required to confirm reliable results for efficacy of PRP for rotator cuff repair [38]. Over the past few years, increasing studies have been conducted on the application of injection of PRP for the treatment of FS. An existing study suggested that in the rat FS model, PRP injection into the glenohumeral joint inhibited strong structural changes in the posterior synovial membrane of rats in an *in vivo* shoulder contracture model, which did not cause any side effects and was considered to be safe [37]. Havva et al. [26] found that PRP injection could effectively alleviate pain, improve range of motion of shoulder joint and enhance functionality in patients suffering from FS and chronic shoulder pain. In 2020, Hüma et all. injected PRP into the shoulder joint of a patient with chronic kidney disease and it was found that the symptoms of FS could be mitigated [33]. Some studies have qualitatively evaluated the safety and efficacy of PRP injection in FS. Although numerous studies have reported that PRP injection is a promising alternative treatment option for FS, there have been rare clinical trials for quantitative analysis to prove this theory. In this study, the clinical literature related to the use of topical PRP injections for the treatment of FS was comprehensively searched. Relevant literature was combined through systematic reviews and meta-analyses. The aim of this study was to understand the efficacy of local injection of PRP in the treatment of FS and to compare the efficacy of PRP with conservative treatment.

2. Methods

The meta-analysis was registered in INPLASY under registration number INPLASY202060097.

2.1. Literature search

Seven electronic databases including PubMed, EMBASE, Web of Science, Elsevier, The Cochrane Library, WanFang Data and CNKI, as well as the references of related experiments, were searched using from the time of establishment of the database to May 31, 2020. The search criteria adopted a combination of subject words and free words: "Frozen Shoulder", "Bursitides" [Mesh], "Pes Anserine Bursiti*", "Adhesive Capsuliti*" or "Adhesive Capsulitis of the Shoulder", and "platelet-rich plasma" [Mesh], "platelet-rich fibrin

matrix", "platelet gel" or "PRP", using the Boolean operator "and or". This study included all published randomized controlled trials as well as prospective cohort studies. Pretrials, observational studies, case reports, reviews, and basic or animal studies were excluded.

2.2. Inclusion criteria

Patients older than 18 years old with a clinical diagnosis of FS (pain caused by active extension of shoulder pronation and elbow extension according to symptoms).

2.3. Exclusion criteria

Disorder was secondary to inflammatory joint disease; Presence of any kind of shoulder musculoskeletal pathological or neurological disorder; Anemia (hemoglobin level $<$ 9 g/dl); Poorly controlled diabetes; Severe cognitive impairment; Unable to cooperate with rehabilitation training; Patients with any form of shoulder surgery.

2.4. Quality assessment of the studies

Two evaluators evaluated the bias risk included in the study according to the bias risk assessment tool for RCT in the Cochrane manual, and the prospective study was evaluated in the form of non-random study indicators. Differences were resolved by consensus or through consultation with senior inspectors.

2.5. Data extraction

Two researchers independently screened the literature, extracted the data and cross-checked them. If any objections were present, they were discussed and resolved amongst themselves or were referred to a third researcher for assistance. If there was a lack of information, the original author was attempted to be contacted for supplementation. The extracted data included: The basic information contained in the study included the authors' names, year of publication and country basic characteristics of the subjects including sample size and age details of the intervention and treatment process key elements of bias risk assessment, and key data on outcome indicators.

2.6. Statistical analysis

Since different follow-up times were used in the included articles, we collected and calculated data over approximately the same time range. The data for the first month and the third week were combined, and the follow-up data for the twelfth week and the third month were combined. The average difference (MD) and 95% CI were calculated using continuity variables for VAS score and ROM improvement. Here, $\chi \sim 2$ was used to include heterogeneity between the results of the study. The test was then carried out (the test level was $\alpha = 0.1$), and heterogeneity was quantitatively judged by I2 If no statistical heterogeneity was present among the results of each study, the fixed effect model was used for the meta-analysis. If statistical heterogeneity existed between the results of each study, the source of heterogeneity was further analyzed. After excluding the influence of obvious clinical heterogeneity, the random effect model was used for the meta-analysis. To evaluate the presence of small-study effects in the meta-analysis, Egger's test was performed. The publication bias was assessed by testing the relationship between the treatment effects and the standard error of the estimate through Egger's test.

3. Results

3.1. Study identification and selection

Figure 1 depicts the study selection and inclusion. Accordingly, potential studies were initially detected, and following a layer-by-layer screening, one prospective study and three randomized trials were included in the final quality assessment and data extraction. Of the four studies [17–20], three reported a VAS ($n = 295$) while three reported a ROM ($n = 299$). The literature screening process and results are shown in Fig. 1.

3.2. Risk of bias assessment

All trials were assessed by two reviewers in accordance with the Cochrane Manual Risk of Bias assessment tool to assess the bias in the included studies (Figs 2 and 3). One of the included studies was a prospective cohort study using the Newcastle-Ottawa Scale (NOS) for assessment [20] (Fig. 3). Sequence generation and allocation were adequately reported by two studies [18,19], except for one study [17] where the concealment of allocation from the investigators and sequence generation was unclear (unclear risk of bias). Two studies [18,19] were considered at a low risk for detection bias because of the blinding of the outcome assessor, except for one study [17] in which the outcome assessor was not reported (unclear risk of

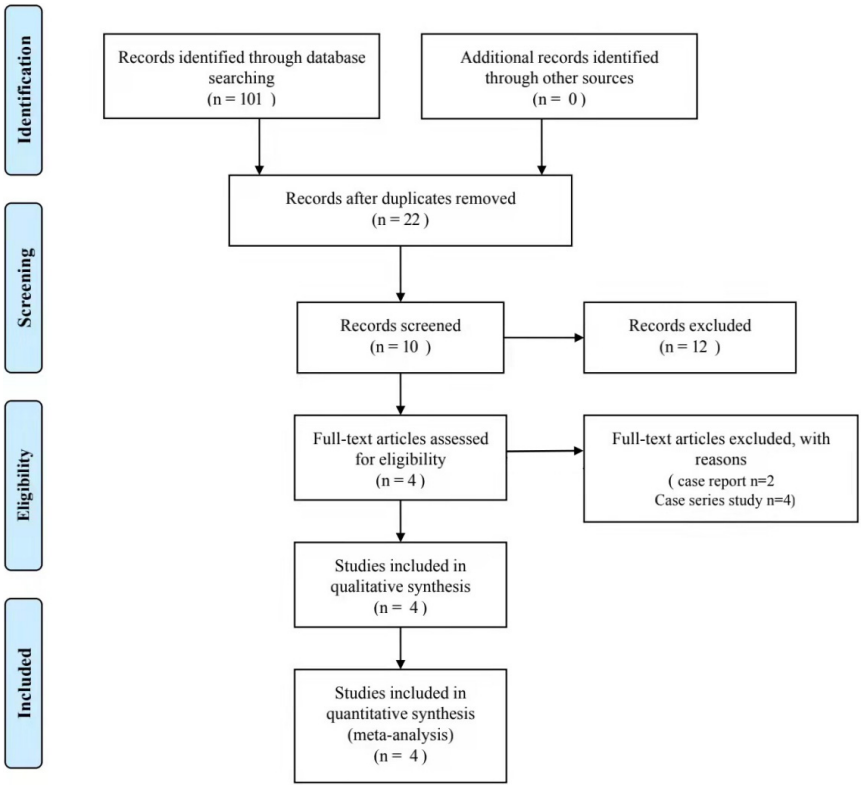

Fig. 1. Flow diagram of study inclusion.

bias). Patients in two studies [18,19] were blinded to their intervention group (low risk of bias), except for one study [17] in which the patients were not blinded to their intervention group (unclear risk of bias). None of the studies reported significant loss of follow-up (low risk of bias).

3.3. Research characteristics

Of the included studies, one study compared PRP with procaine+CS, one compared PRP with CS and ultrasound therapy, one compared PRP+Ketamine+ Bupivacaine in combination with SGB+Ketamine+ Bupivacaine, and another compared PRP injection with CS+lidocaine injection. All studies included physical exercise. The total number of people was 356 and the average sample size was 40 patients in this study. The average age of the patients included was 53 years old, where 55% were female and the average duration of symptoms was 5 months. Two studies had a final follow-up at about 6 months, while the other two studies had a final follow-up at 12 weeks (Table 1).

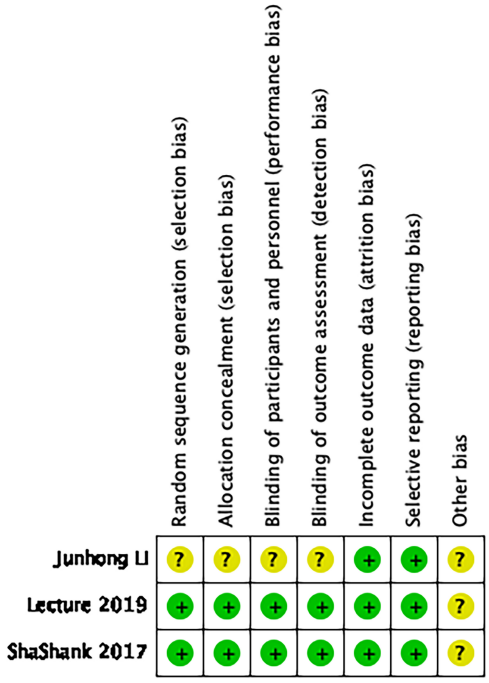

Fig. 2. Quality assessment of RCT studies.

Table 1
Characteristics of the included studies

Reference	Group	Age (years)	Numbers	Intervention	Outcome measure	Follow-up
Lin et al. [17]	PRP, Procaine+CS	59.8 ± 4.3 58.2 ± 4.6	N = 30 N = 30	3 times, 2 ml, every 2 weeks	VAS, UCLA	1w, 1m, 3m, 6m
Shashank et al. [18]	PRP, CS, Ultrasonic therapy	51.9 ± 10.1 52.7 ± 8.6 51.2 ± 11.7	N = 62 n = 60 n = 58	Single injection 2 ml, single injection 2 ml (80 mg), 7 minutes 1.5 W/cm^2, 1 MHz, continuous mode on alternate days for 14 days	VAS, QuickDASH, ROM	3w, 6w, 12w
Lecturer et al. [19]	SGB+Ketamine+ Bupivacaine, PRP+Ketamine+ Bupivacaine	55.2 ± 7.9 51 ± 10.3	N = 32 N = 32	Single, SGB+Ketamine (5 ml) + Bupivacaine (5 ml), Single, SGB+PRP (5 ml) + saline (5 ml), 3 times with 1 week interval	NRS, QuickDASH, ROM	1m, 3m, 6m
Barman et al. [20]	PRP, CS+Lidocaine	50.0 ± 6.31 50.26 ± 5.94	n = 28 n = 27	Single injection 4 ml, single injection (CS 2 ml + Lidocaine 2 ml)	VAS, ROM	3w, 6w, 12w

Abbreviations: PRP: platelet-rich plasma; CS: Corticosteroid; DASH: Disabilities of the Arm, Shoulder and Hand Score; ROM: range of motion, shoulder joint; VAS: visual analog scale; UCLA: University of California at Los Angeles Shoulder Scale; SGB: stellate ganglion block; NRS: Numerical Rating Scale.

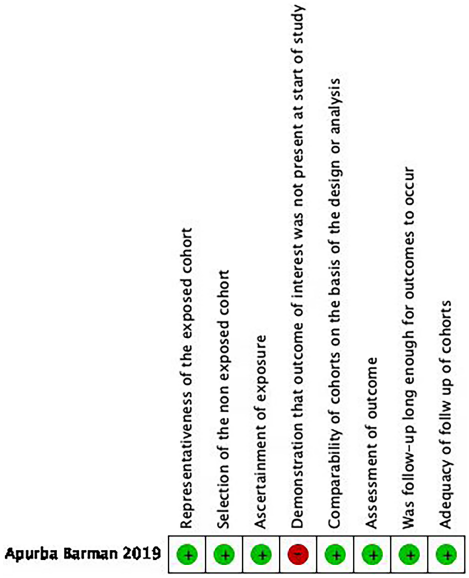

Fig. 3. Quality assessment of nonrandomized trials.

3.4. Meta-analysis results

Among the included studies, VAS and ROM were the most commonly used tools in evaluating the efficacy of PRP injection or other treatments. The data of the first and third months after the intervention were calculated. According to the data provided when the study summarized the data, there was no significant difference in the standardized mean of VAS score at enrollment (SMD: −0.04, 95% CI: −0.34 to 0.26 $P = 0.794$ $I^2 = 48.4\%$ Fig. 4). At 1 month and 3 months of treatment, the PRP group was observed to be superior compared to groups adopting other treatments (SMD: −0.46, 95% CI: −0.75 to −0.18 $P = 0.002$, $I^2 = 43.2\%$ Fig. 5) and (SMD: −0.87, 95% CI: −1.23 to −0.50 $p = 0.00$, $I^2 = 61.9\%$, Fig. 6). There was a publication bias according to the symmetry of the Egger test (Figs 7 and 8).

The range of motion of the shoulder joint consists of four parts: internal rotation, flexion, external rotation and abduction. The results showed that the internal rotation, external rotation and abduction were all improved in the PRP treatment group, compared to the control group at 1 month (SMD: 0.53, 95% CI: 0.02 to 1.04, $p = 0.043$, $I^2 = 81.8\%$ Fig. 9), (SMD: 0.37, 95% IC: 0.09 to 0.65, $p = 0.010$, $I^2 = 41.6\%$ Fig. 10), (SMD: 0.88, 95% IC: 0.10 to 1.65, $p = 0.026$, $I^2 = 91.4\%$ Fig. 11). However, no significant improvement was present in the flexion motion in the PRP group compared to the control group at 1 month (SMD: 0.32, 95% CI: −0.64 to 1.28, $p = 0.513$, $I^2 = 94.7\%$ Fig. 12). At 3 months, internal rotation, external rotation, flexion and abduction were improved in the PRP group, compared with the control group (SMD: 0.92, 95% CI: 0.53 to 1.30, $p = 0.000$, $I^2 = 58.6\%$, Fig. 13), (SMD: 0.65, 95% CI: 0.34 to 0.96, $p = 0.000$, $I^2 = 40.5\%$, Fig. 14), (SMD: 0.98, 95% CI: 0.50 to 1.45, $p = 0.000$, $I^2 = 72.3\%$, Fig. 15), (SMD: 1.15, 95% CI: 0.50 to 1.79, $P = 0.000$, $I^2 = 84.1\%$, Fig. 16) (Table 2).

4. Discussion

This is the first systematic review with meta-analysis performed to evaluate the efficacy of nonoperative PRP injections for FS. The systematic review suggested that patients who received the treatment for FS with PRP injections could be expected to have improved clinical outcomes at short-term follow-up as compared with patients who received other treatments. Of all clinical out-

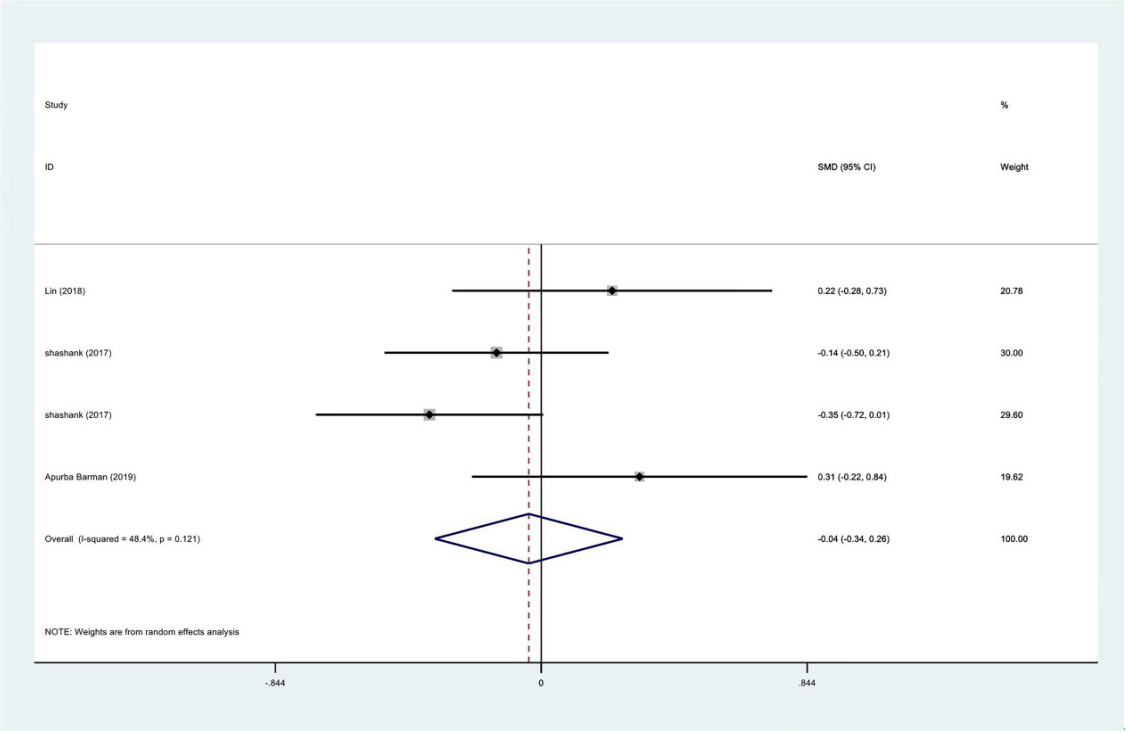

Fig. 4. Meta-analysis results of VAS scores between PRP group and control group before intervention.

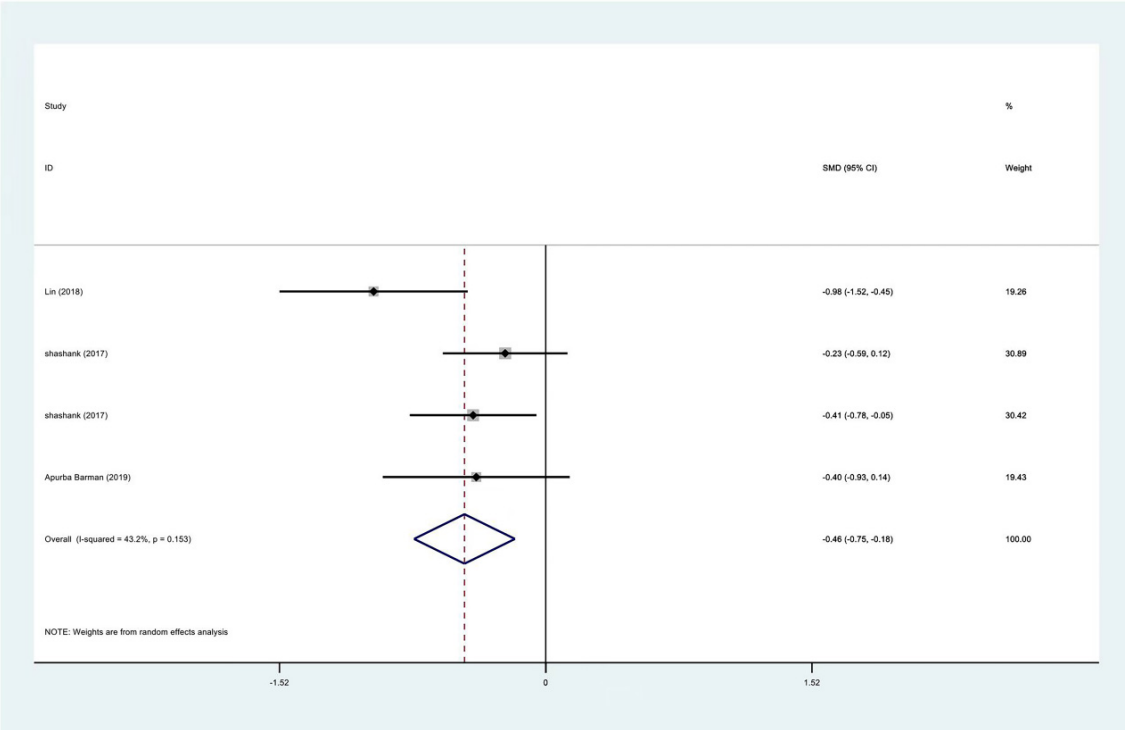

Fig. 5. Meta-analysis results of VAS scores between PRP group and control group at 1 month.

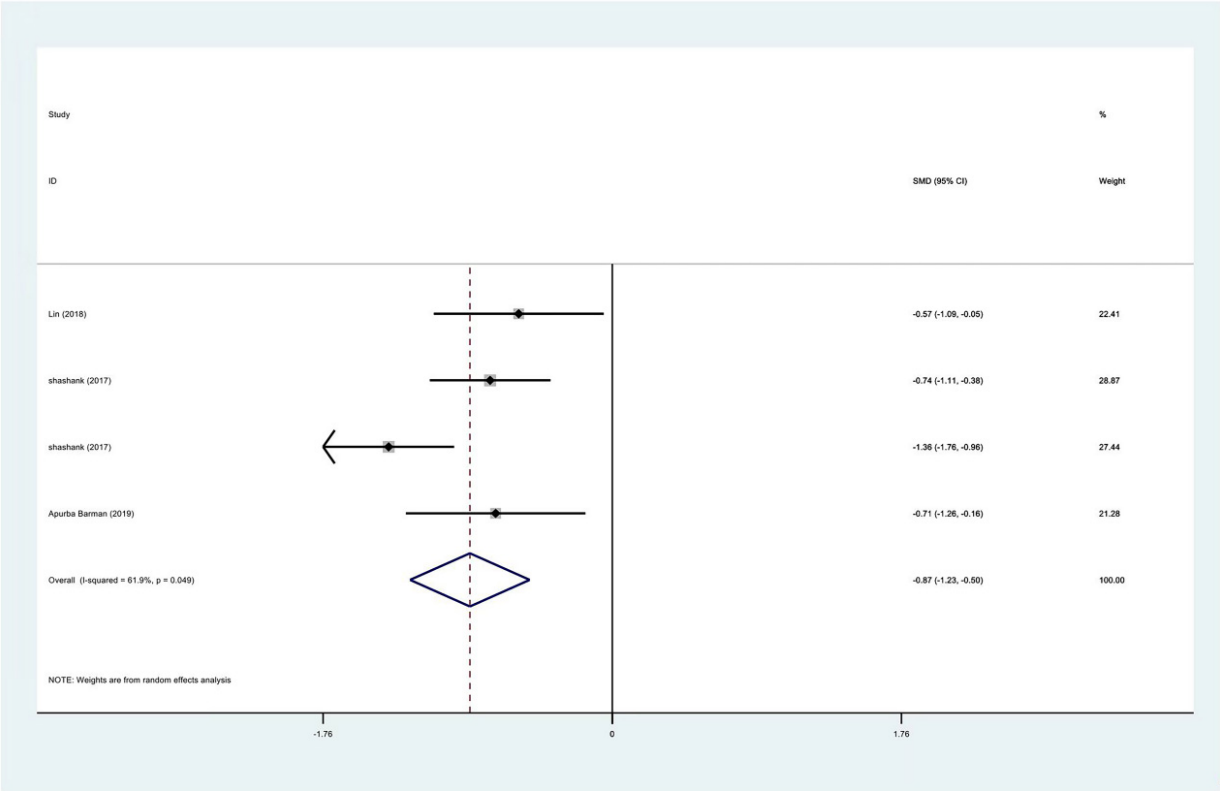

Fig. 6. Meta-analysis results of VAS scores between PRP group and control group at 3 months.

Egger's regression intercept

Intercept	6.62355
Standard error	0.67005
95% lower limit (2-tailed)	3.74055
95% upper limit (2-tailed)	9.50656
t-value	9.88513
df	2.00000
P-value (1-tailed)	0.00504
P-value (2-tailed)	0.01008

Fig. 7. Egger test of VAS scores between PRP group and control group at 1 month.

Egger's regression intercept

Intercept	-0.73236
Standard error	4.56674
95% lower limit (2-tailed)	-20.38146
95% upper limit (2-tailed)	18.91675
t-value	0.16037
df	2.00000
P-value (1-tailed)	0.44366
P-value (2-tailed)	0.88733

Fig. 8. Egger test of VAS scores between PRP group and control group at 3 months.

comes assessed in this systematic review, PRP injection was more effective than other treatments with regards to pain relief and functional improvement in FS patients and had fewer side effects. However, in this systematic review, limited high-quality studies regarding the use of non-operative PRP in FS were identified. There were only three randomized controlled trials and one cohort study. All studies had relatively limited sample sizes between 60 to 120 participants. All qualifying trials had different PRP injection protocols including four trials that utilized multiple serial PRP injections with varying intervals. Accordingly, although all included studies have reported that PRP has a significant therapeutic effect on patients with FS compared with other treatments, considerable high-quality clinical studies are still needed in the future.

The better efficacy of PRP in the treatment of FS may be related to the pathogenesis of FS. Although the pathogenesis of FS has not been fully elucidated, it is recognized that it is chronic aseptic inflammation. Various studies have shown that inflammatory cytokines such as tumor necrosis factor-α, interleukin-1 α (IL-1 α), interleukin-1 β and interleukin-6 are present in the glenohumeral joint andsubacromial bursa [25]. Chronic

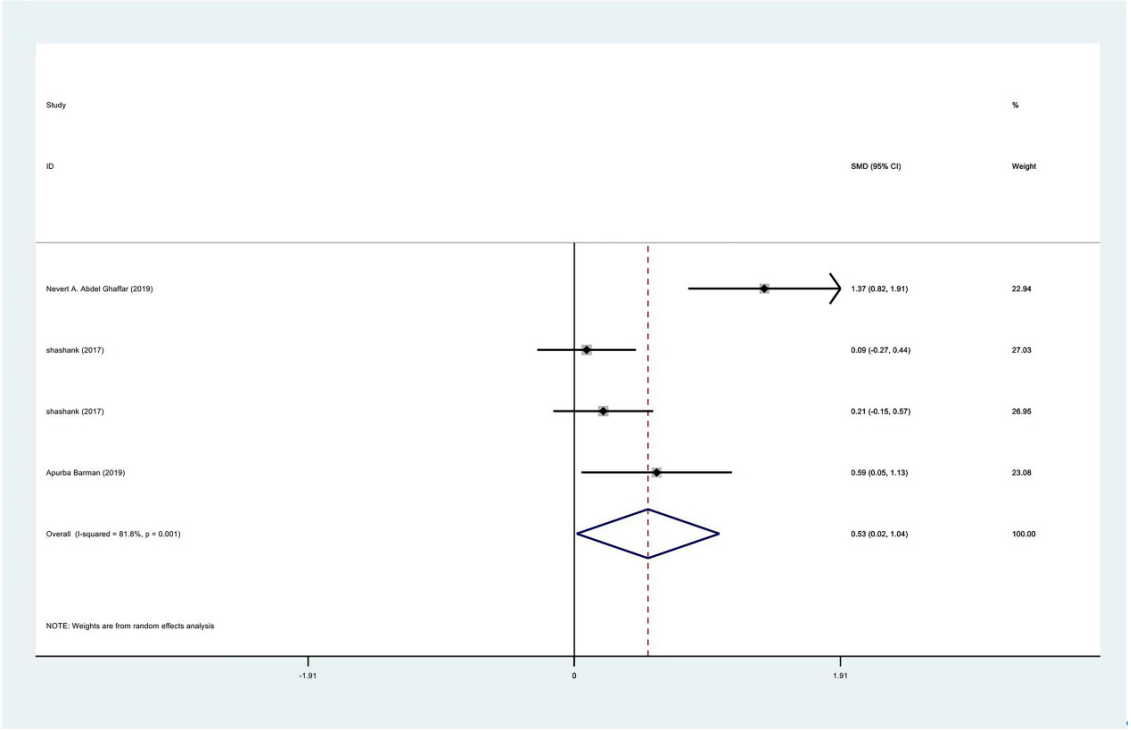

Fig. 9. Meta-analysis results of internal rotation between PRP group and control group at 1 month.

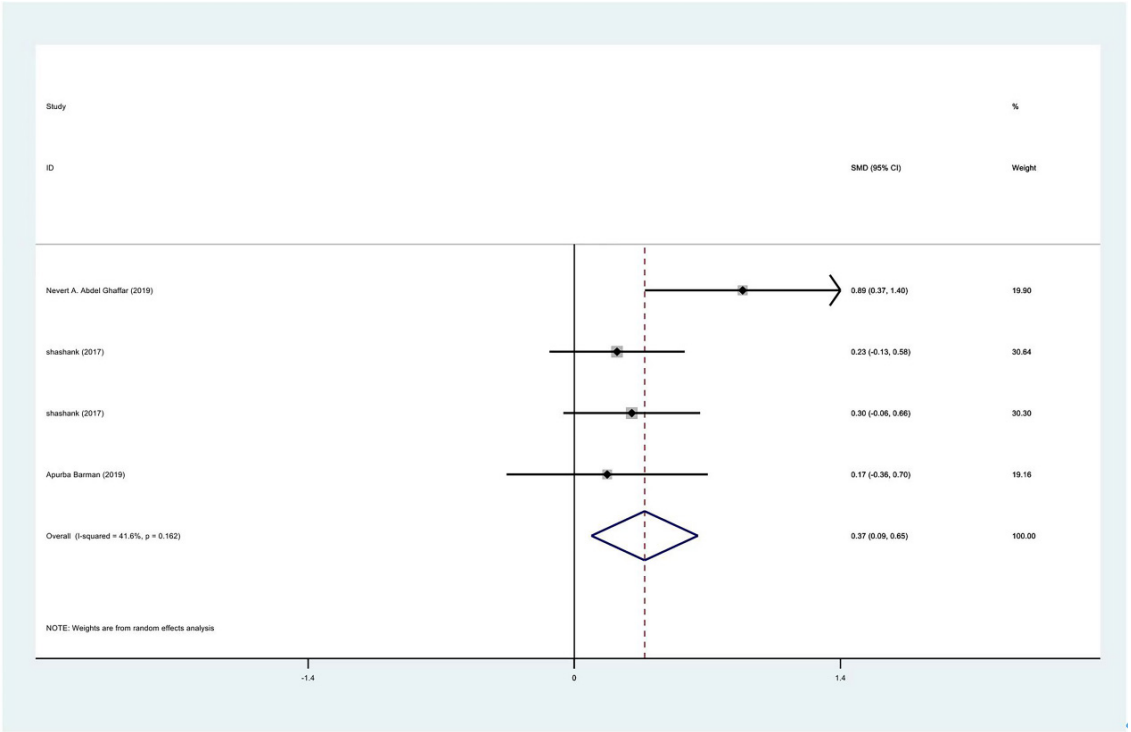

Fig. 10. Meta-analysis results of external rotation between PRP group and control group at 1 month.

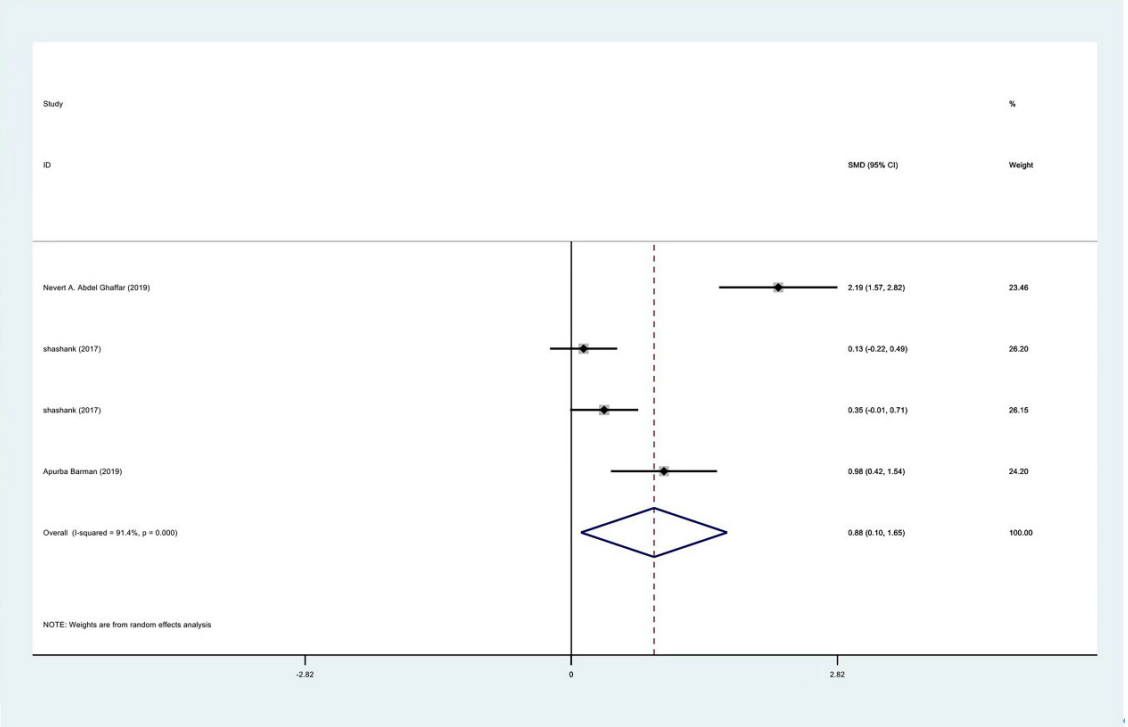

Fig. 11. Meta-analysis results of abduction between PRP group and control group at 1 month.

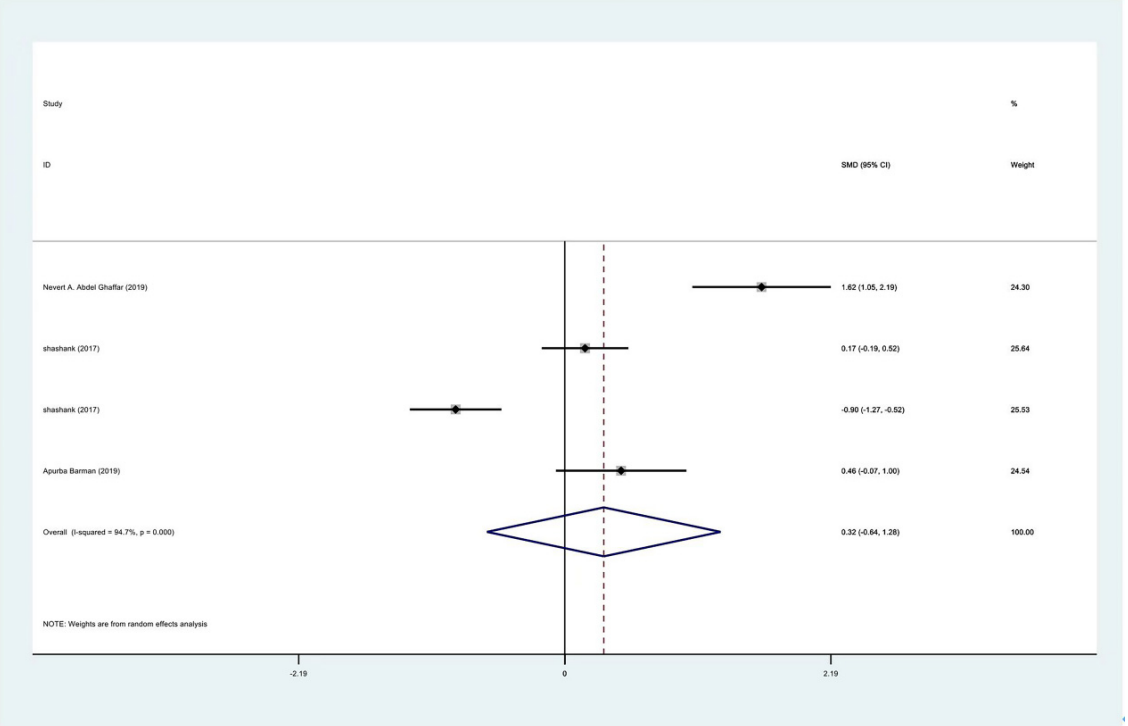

Fig. 12. Meta-analysis results of flexion between PRP group and control group at 1 month.

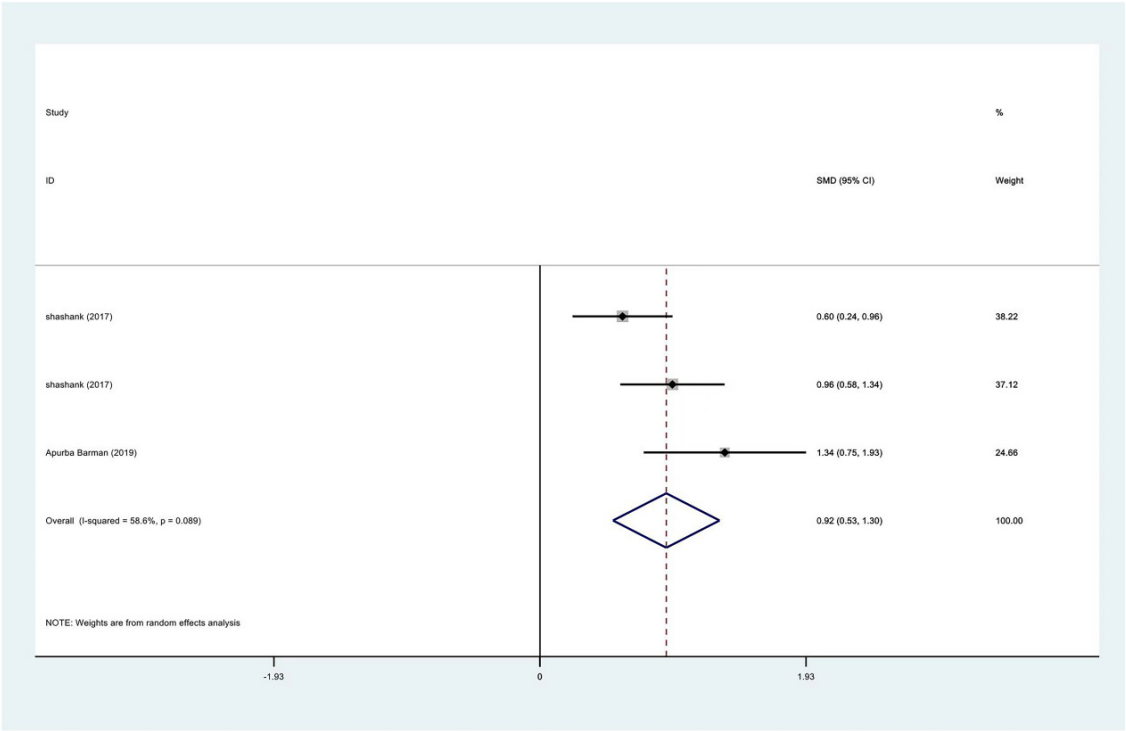

Fig. 13. Meta-analysis result of internal rotation between PRP group and control group at 3 months.

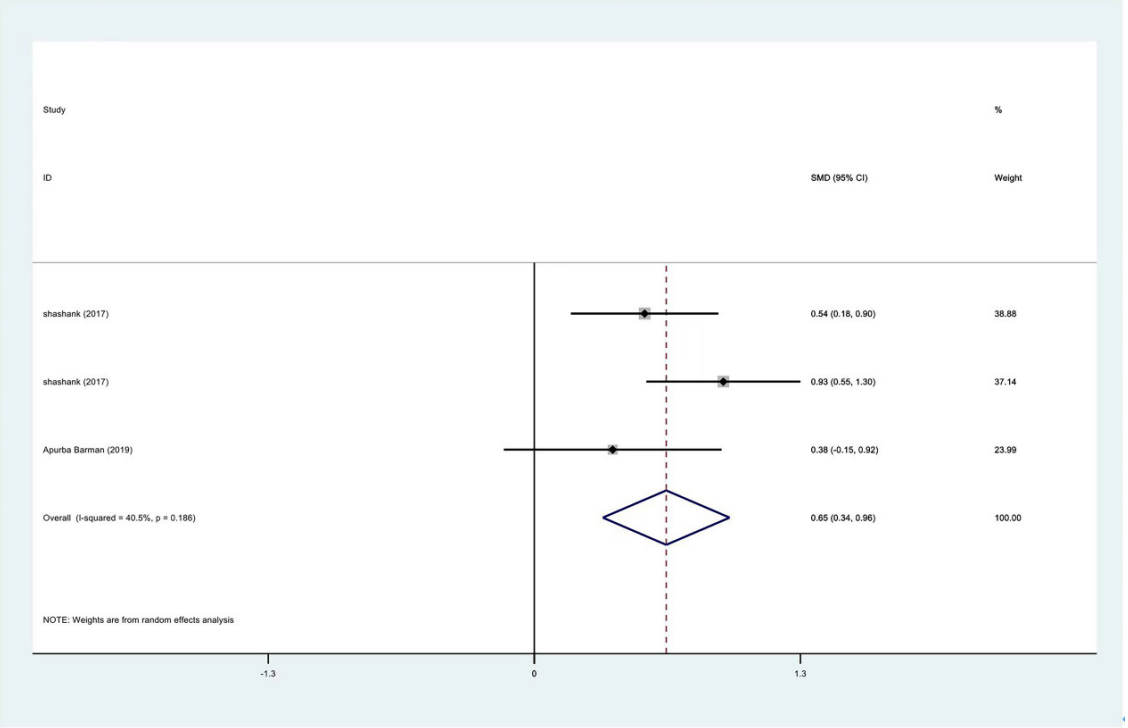

Fig. 14. Meta-analysis results of external rotation between PRP group and control group at 3 months.

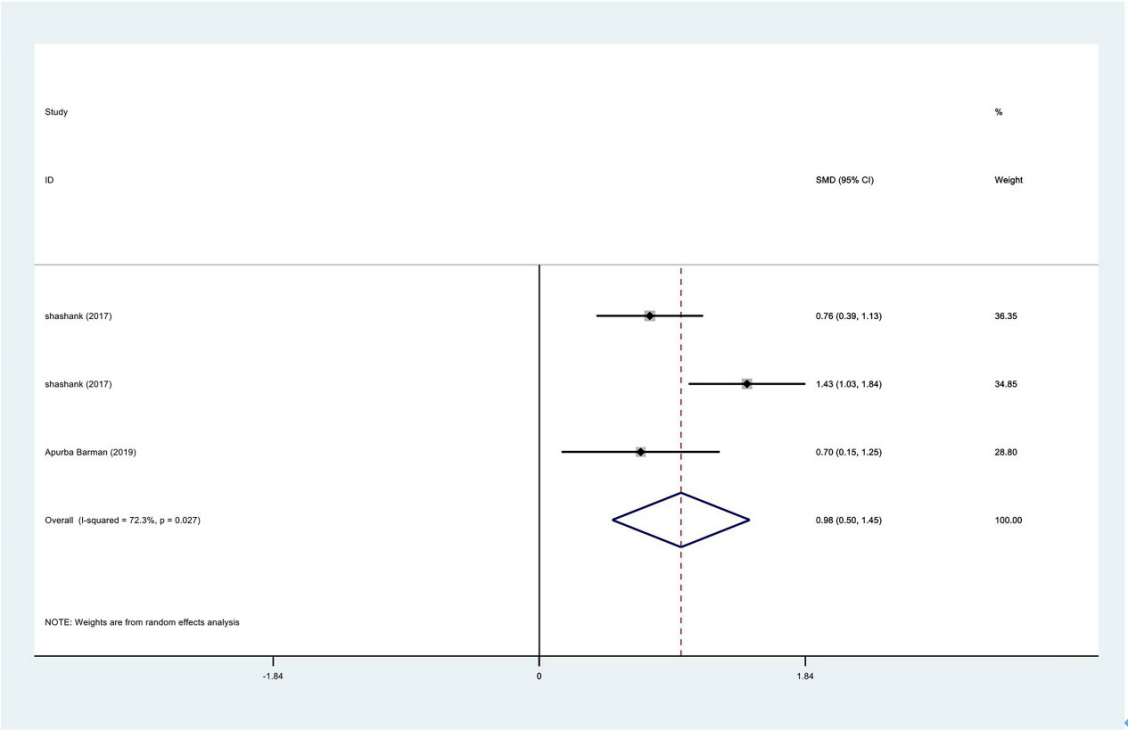

Fig. 15. Meta-analysis results of flexion between PRP group and control group at 3 months.

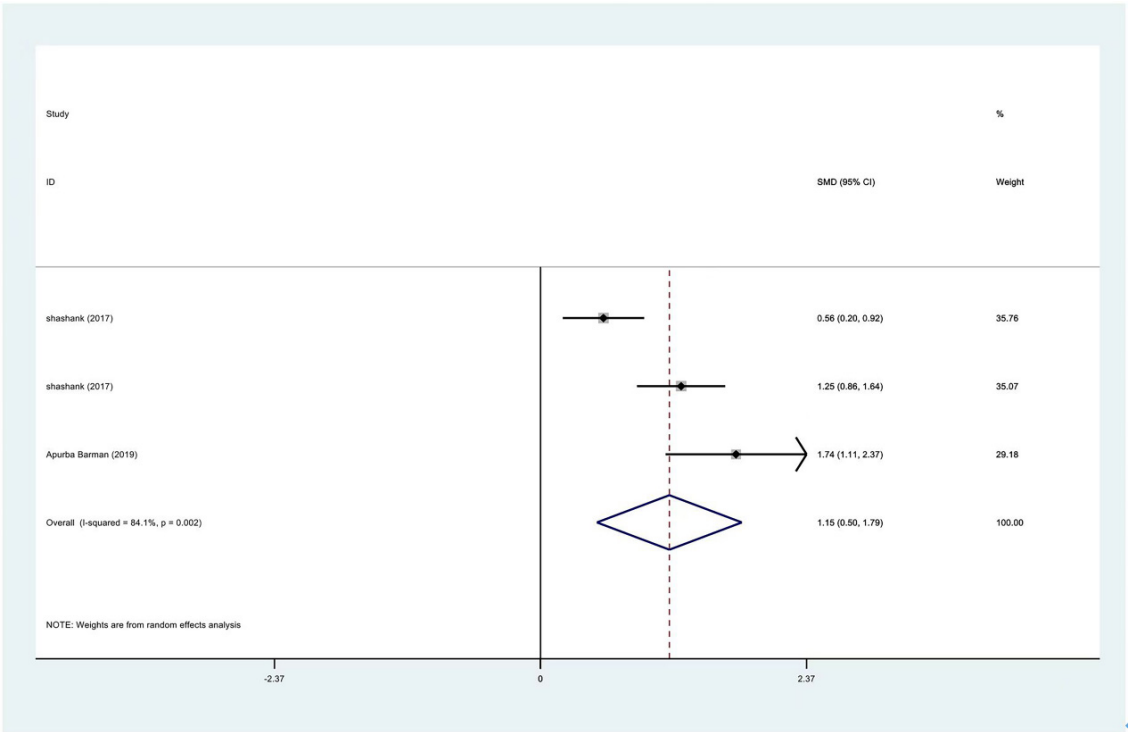

Fig. 16. Meta-analysis results of abduction between PRP group and control group at 3 months.

Table 2
Results of the meta-analysis

Follow-up	Evaluation tools	Studies	Patients (PRP/other treatments)	SMD	95% CI	$P < 0.05$	I2
1 month	VAS	3	120/175	−0.46	−0.75 to −0.18	Yes	43.20%
	Internal rotation	3	122/177	0.53	0.02 to 1.04	Yes	81.80%
	Flexion	3	122/177	0.32	−0.64 to 1.28	No	94.70%
	External rotation	3	122/177	0.37	0.009 to 0.65	Yes	41.60%
	Abduction	3	122/177	0.88	0.10 to 1.65	yes	91.40%
3 months	VAS	3	120/175	−0.87	−1.23 to −0.50	Yes	61.90%
	Internal rotation	3	122/177	0.92	0.53 to 1.30	Yes	58.60%
	Flexion	3	122/177	0.98	−0.50 to 1.45	Yes	72.30%
	External rotation	3	122/177	0.65	0.34 to 0.96	Yes	40.50%
	Abduction	3	122/177	1.15	0.50 to 1.79	Yes	84.10%

inflammation can lead to synovial thickening and fibrosis in the articular capsule, where active fibroblasts and myofibroblasts proliferate, causing the articular capsule to proliferate and adhere to itself and the anatomical neck of the humerus [24]. Muscle contraction, traction and adhesion of synovium cause pain, and fibrosis leads to a decrease in the elasticity of soft tissue and a decrease in the effective volume of the glenohumeral joint, which eventually causes limited movement of the shoulder joint. Feusi et al. [37] showed that PRP injection into the glenohumeral joint prevented strong structural changes in the posterior synovial membrane of rats in an *in vivo* shoulder contracture model and there were no clinical side effects observed. They proved a beneficial effect of PRP, probably by downregulating the inflammatory responses in this model of secondary FS. A recent study has shown that PRP could downregulate the gene expression of proinflammatory cytokines such as IL-1b, TNF-a, IL-6, COX-2, and mPGES-1 under the inflammatory condition. It was suggested that PRP may modulate inflammation related cytokines to relieve pain and improve the ROM score in patients with FS [41]. Consequently, PRP may have several important biological advantages that should be considered when providing treatment for FS.

Recently, PRP has been widely studied and developed in the field of basic disciplines and has been proven to repair chronic muscle injury by basic experiments and clinical studies around the world. Hammond et al. [27] showed that in repeated small stress stretch, muscle activity was significantly improved in a muscle injury model, and the recovery time was shortened after treatment with PRP. Bubnov et al. [28] found that during the one-month follow-up, compared to conventional conservative treatment, ultrasound-guided PRP injection plus conservative treatment was found to be more effective in relieving pain in athletes with acute muscle injury, and the scores of muscle strength and subjective function were observed to be significantly improved. Christos et al. [34] found that during the 6-month follow-up, compared to whole blood injection, PRP injection significantly relieved pain in tennis elbow. Another 2-year follow-up study demonstrated that PRP injection improved upper limb function and relieved pain in patients with chronic lateral epicondylitis compared to corticosteroid injection. These results were consistent with the effect of PRP injection in the treatment of patients with FS, indicating that PRP has advantages in the treatment of chronic injury.

The largest advantage of this study is its novelty. Currently, no meta-analysis exists that studies the efficacy of PRP injection in the treatment of FS. However, this study has various limitations. First, the sample sizes were small, the heterogeneity of some studies was high, which may lead to overestimation of the therapeutic effect. However, since there were fewer included studies, it is impossible to carry out a subgroup analysis. In order to obtain more accurate results, more randomized controlled trials should be conducted with larger sample sizes. Second, the lack of the different protocols used in PRP preparation and administration. Finally, included studies contained methodological defects, which may affect the persuasive power.

5. Conclusions

The duration of this study was limited to 3 months, hence, the long-term effect is not clear. Overall, available evidence suggests that for patients with FS, PRP can effectively relieve pain and improve ROM in patients with FS in the short term (3 months), compared to other non-operative treatments. However, this form of therapy is limited by quantity, quality and follow-up time of the included studies. Therefore, the above conclusions must be confirmed by conducting additional high-quality studies.

Ethical approval

Not applicable.

Funding

None to report.

Informed consent

Not applicable.

Acknowledgments

The authors thank all participants in the study.

Conflict of interest

The authors have no conflicts of interest to declare.

Author contributions

RH and S-ZY designed and performed the experiments, collected and analyzed data, and wrote the manuscript. H-MF and HD provided valuable advice on the design of this study. DH and LY provided valuable advice on research and guided the completion of this experiment. All authors read and approved the final manuscript.

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