

Review Article

Efficacy of Shengjing capsules for treatment of male infertility in China: a systematic review and meta-analysis

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Received November 5, 2018; Accepted March 13, 2019; Epub June 15, 2019; Published June 30, 2019

Abstract: The aim of the current study was to evaluate the efficacy of Shengjing (SJ) capsules for treatment of male infertility in China. Present researchers searched China National Knowledge Infrastructure (CNKI) database, Wanfang Database, VIP Science and Technology Periodical Database, China Biology Medicine Database (CBM), Cochrane library, PubMed, Embase, Clinicaltrials.org, and Chinese academic conference papers. Selection of randomized controlled trials (RCTs), before June 2018, was made concerning the effects of SJ capsule on male infertility, evaluated by Jadad scale scores. Data was analyzed with RevMan 5.3 and Stata/SE 14.1 software. A total of twenty-two randomized clinical trials (RCTs), involving 2,393 patients (1,201 patients in the trial group and 1,192 patients in the control group), were included. The total treatment risk ratio (RR) was 1.43 (95% IC: 1.29-1.60). Merged RRs of the single-drug group and combined group were 1.70 (95% IC: 1.21, 2.39) and 1.34 (95% IC: 1.22, 1.46), respectively. Incidence of adverse events was low in all studies. SJ capsule are a new option for treatment of male infertility. However, high quality multi-centered, randomized, parallel-controlled, and blinded trials are necessary to confirm the safety and efficacy of SJ capsules. This requires further examination of treatment of male infertility with SJ capsules.

Keywords: Male infertility, Shengjing capsule, Traditional Chinese Medicine, systematic review, meta-analysis

Introduction

More than 15% of married couples, worldwide, suffer from fertility problems. Approximately 50% are caused by male infertility [1]. In China, it has been reported that the semen quality of men has decreased at a rate of 1% per year [2], significantly affecting family harmony and health in men. Male infertility is not an independent disease. It is a result of many factors, with idiopathic infertility accounting for 30% of cases of male infertility [3]. Therefore, many drugs could be used to treat the disease, especially antioxidants. Antioxidants, such as glutathione, vitamins E and C, carnitines, coenzyme-Q10, N-acetylcysteine, selenium, zinc, folic acid, and lycopene, have been shown to reduce OS-induced sperm damage. Recent systematic reviews and meta-analyses have reported the beneficial effects of antioxidants on semen parameters [4]. With no specific drugs for idio-

pathic male infertility, there is an opportunity for Traditional Chinese Medicine or integrated Traditional Chinese and Western medicine to treat this disease.

Recently, a pure Traditional Chinese Medicine preparation, Shengjing (SJ) capsule have been widely used for treatment of male infertility in China. These capsule are composed of *Pilose antlers*, *Chinese wolfberry*, *Ginseng*, *Cordyceps sinensis*, *Semen cuscutae*, *Astragalus membranaceus* (Fisch.), *Aceranthus sagittatus* S. et Z., *Polygonatum sibiricum* red., *Polygonum multiflorum*, *Mulberry*, *Fructus psoraleae*, *Rhizoma drynariae*, *Curculigo orchioides* gaertn., *Fructus rosae laevigatae*, *Fructus rubi*, *Eucommia ulmoides*, *Sargentg loryvine stem*, *Herba verbenae*, and *ginkgo leaves*. SJ capsule can increase antioxidant enzyme activity and inhibit oxidative stress. They can repair pathological damage of the testis and epididymis, protect again-

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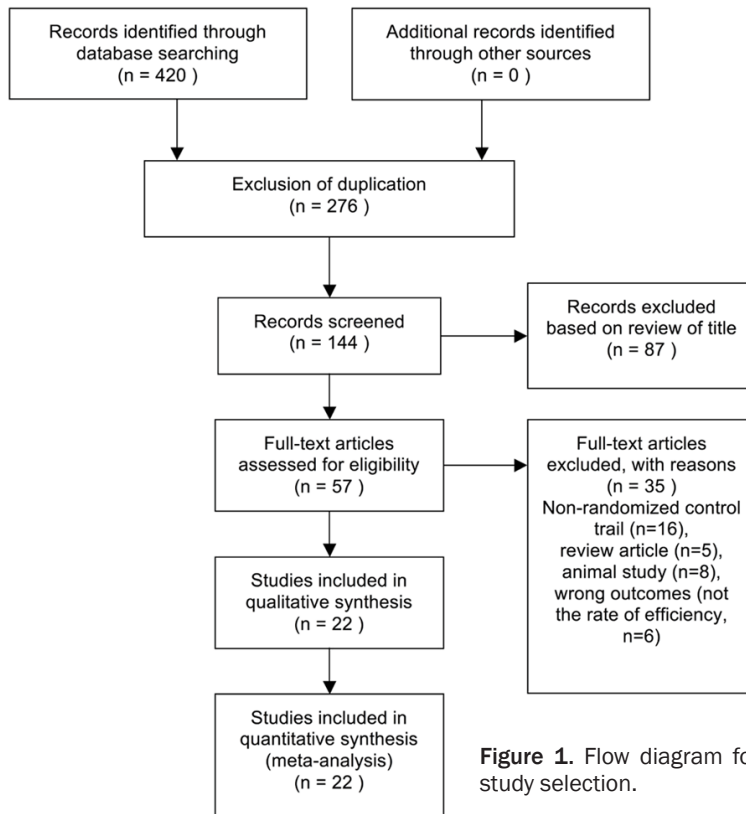


Figure 1. Flow diagram for study selection.

st spermatogenesis, increase the number and vitality of sperm, and improve normal morphology rates of sperm [5]. At present, there are no definite drugs for treatment of male infertility. In view of the good curative effects of Traditional Chinese Medicine SJ capsules for treatment of male infertility in China, the purpose of this study was to evaluate the effectiveness of SJ capsule, according to completed randomized clinical trials (RCTs). This study aimed to provide a choice for andrologists and urologists concerning treatment of male infertility.

Material and methods

The current systematic review and meta-analysis was carried out in strict accordance with the guidelines of Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA). Since the purpose of this meta-analysis was to summarize previous studies, ethical approval and informed consent were not necessary.

Study search and trail selection

Present researchers searched various electronic databases, including China National Kn-

owledge Infrastructure Database (CNKI), Wanfang Database, China Biology Medicine Database (CBM), VIP Science and Technology Periodical Database, Cochrane library, PubMed, EMBASE, Clinicaltrials.org., and Chinese academic conference papers. They collected and selected related studies, before June 2018, concerning SJ capsule therapy for male infertility. Search terms included: “[Shengjing Capsules AND (male infertility) OR (sperm quality)]”. **Figure 1** shows a flow chart detailing study selection. Studies with RCTs of SJ capsules for male infertility were included. Inclusion criteria: Participants experienced male infertility. The aim of this study was to compare the efficacy of SJ capsules with other Western medicines; Outcomes contained effective rates or adverse ev-

ents; Abstracts of relevant conferences of randomized controlled trials were included in the analysis based on the recommendations of Systematic Reviews section 6.2.2.4 in Cochrane Handbook [6]. Exclusion criteria: Articles unrelated to the current analysis; Lacked essential information concerning patients and intervention measures of treatment; Non-original research, reviews, and comments. There were no restrictions on language or minimum patients of the study. Only the largest or most recent studies were included when similar patients and same detection methods were used.

Data extraction and quality assessment

Related data of included articles was extracted, independently, by 3 investigators, according to the PRISMA statement. All discrepancies were resolved through adjudication and discussion with other reviewers. First, words in abstracts, such as “randomized” or “quasi-randomized”, were used in all studies, regardless of whether they were blinded or not. For each study, the following information was extracted: First author’s name, year of publication, study design, participant characteristics, interven-



Figure 2. There were 22 randomized controlled studies included in the meta-analysis. The quality of studies was assessed with the Cochrane Collaboration's tool.

Statistical analyses

Statistics analyses were conducted using RevMan 5.3 and Stata/SE 14.1. Statistical tests were two-sided, with P-values less than 0.05 indicating significance. Egger's and Begg's tests were used for investigation of publication bias due to small study effects [9]. Risk ratios (RR) were estimated for dichotomous data. I-squared and P-values were used to estimate statistical heterogeneity between trails. If heterogeneity existed (P< 0.05), data was analyzed using a random-effects model. In the absence of heterogeneity, a fixed-effects model was used.

Results

Characteristics of included trials

A total of 420 potential conformity tests were screened through preliminary searches of the databases, including electronic and manual searches. Subsequently, 22 RCTs were eligible for inclusion by deleting duplicated publication trials, those with no data for extraction, case reports, those with inappropriate controls, drug combinations, and no specific course of disease, intervention studies, literature reviews, and animal trials. All tests compared SJ capsules

with Western medicine. Twenty-two RCTs were published in Chinese from 2007 to 2017. All studies were conducted in China. Characteristics of eligible RCTs are listed in Table 1. Included studies were Bai SY 2007 [10], Song FW 2009 [11], Wang T 2009 [12], Wang Z 2009 [13], Cao YL 2010 [14], Li XW 2010 [15], Ji MY 2011 [16], Li H 2011 [17], Liu JP 2011 [18], Su Y 2011 [19], Cao YL 2012 [20], Huang YG 2012 [21], Ji MY 2012 [22], WU LC 2012 [23], Xiong FX 2012 [24], Wang YS 2013 [25], WU LC 2013 [26],

tion, and effective rates of treatment and adverse events. Graphs and summaries, concerning risk of bias, were produced with RevMan 5.3 [7]. Quality of RCTs was evaluated using the Jadad scale [8]. Methods of generating the sequence of randomization, randomization concealment, blinding, withdrawals, and drop-outs were assessed. Figure 2 shows that 52.3% of the studies had an unclear risk of bias in randomization. Only 6.8% of studies had good blinding for both patients and doctors.

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Table 1. Selected characteristics of the 22 studies included in this systematic review

Trail [Ref.]	Year	Sample size	Age, mean (range)	Comparison	Primary outcome	Efficiency (%)	Adverse events	Jadad score
Bai SY [10]	2007	90 (45/45)	22-40	SJ vs Vit C+Vit E	Rate of efficiency	93.3% vs 15.5%	N	2
Song FW [11]	2009	270 (135/135)	27.75 (23-41)	SJ vs Vit E	Rate of efficiency	88.89% vs 33.33%	Y	2
Wang T [12]	2009	102 (51/51)	22-40	SJ vs Vit E+ATP	Rate of efficiency	82.4% vs 33.3%	N	2
Wang Z [13]	2009	60 (30/30)	26.5 (27-40)	SJ+LC+MVCP vs LC+MVCP	Rate of efficiency	86.67% vs 83.33%	N	2
Cao YL [14]	2010	28 (14/12)	25-45	SJ+CG+Indometacin+ZG vs CG+Indometacin+ZG	Rate of efficiency	71.43% vs 50.00%	N	2
Li XW [15]	2010	112 (56/56)	None	SJ vs Clomiphene	Rate of efficiency	89.29% vs 48.21%	Y	2
Ji MY [16]	2011	80 (40/40)	23-39	SJ+LC vs LC	Rate of efficiency	87.5% vs 67.5%	N	2
Li H [17]	2011	96 (50/46)	21-40	SJ+Clomiphene vs Clomiphene	Rate of efficiency	84% vs 60.86%	NM	2
Liu JP [18]	2011	120 (60/60)	None	SJ vs Bromocriptine	Rate of efficiency	76.66% vs 58.33%	NM	2
Su Y [19]	2011	112 (56/56)	20-43	SJ vs Vit E	Rate of efficiency	83.9% vs 43.9%	NM	2
Cao YL [20]	2012	60 (30/30)	28-45	SJ+CG vs CG	Rate of efficiency	86.7% vs 73.3%	N	2
Huang YG [21]	2012	126 (63/63)	22-41	SJ+androgen vs androgen	Rate of efficiency	88.89% vs 68.25%	Y	2
Ji MY [22]	2012	60 (30/30)	22-41	SJ+Proxeed® vs Proxeed®	Rate of efficiency	90% vs 73.3%	NM	2
WU LC [23]	2012	90 (45/45)	24-40	SJ+Vit E+ATP vs Vit E+ATP	Rate of efficiency	93.33% vs 68.89%	N	3
Xiong FX [24]	2012	50 (25/25)	23-43	SJ+Vit E+ATP vs Vit E+ATP	Rate of efficiency	88% vs 68%	N	2
Wang YS [25]	2013	95 (49/46)	24-38	SJ+Vit E+metacortandracin vs Vit E+metacortandracin	Rate of efficiency	91.84% vs 67.39%	NM	3
WU LC [26]	2013	60 (30/30)	21-43	SJ vs ZST	Rate of efficiency	86.67% vs 76.67%	NM	2
Fang TW [27]	2014	80 (40/40)	28.3 (20-39)	SJ+Tamoxifen vs Tamoxifen	Rate of efficiency	90% vs 67.5%	N	2
Song H [28]	2015	440 (220/220)	23-38	SJ+Vit E+ATP vs Vit E+ATP	Rate of efficiency	93.64% vs 71.82%	NM	3
Wei SF [29]	2016	60 (30/30)	21-40	SJ+LC vs LC	Rate of efficiency	73.33% vs 53.33%	NM	2
Zeng YX [30]	2017	80 (40/40)	27-46	SJ+Vit E vs Vit E	Rate of efficiency	90.0% vs 70.7%	NM	2
Shao M [31]	2017	124 (62/62)	20-49	SJ+LC vs LC	Rate of efficiency	90.3% vs 75.8%	NM	2

SJ = Shengjing capsules, LC = L-carnitine, Vit C = Vitamin C, Vit E = Vitamin E, MVCP = Multi vitamin compound preparation, CG = Chorionic gonadotropin, ZG = Zinc gluconate, Proxeed® = L-carnitine (1 g)+Acetyl L-carnitine (0.5 g), ZST = zinc and selenium tablet, PR = Progressive motility, Y = Yes, N = None, NM = Not Mentioned.

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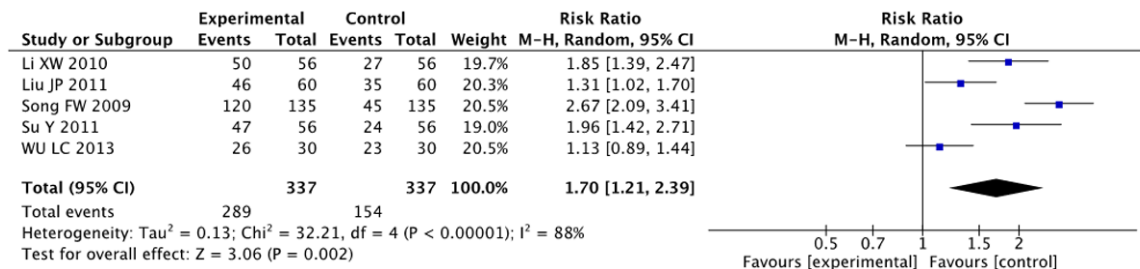


Figure 3. Meta-analysis on the effective rate of SJ capsules in the single-drug group.

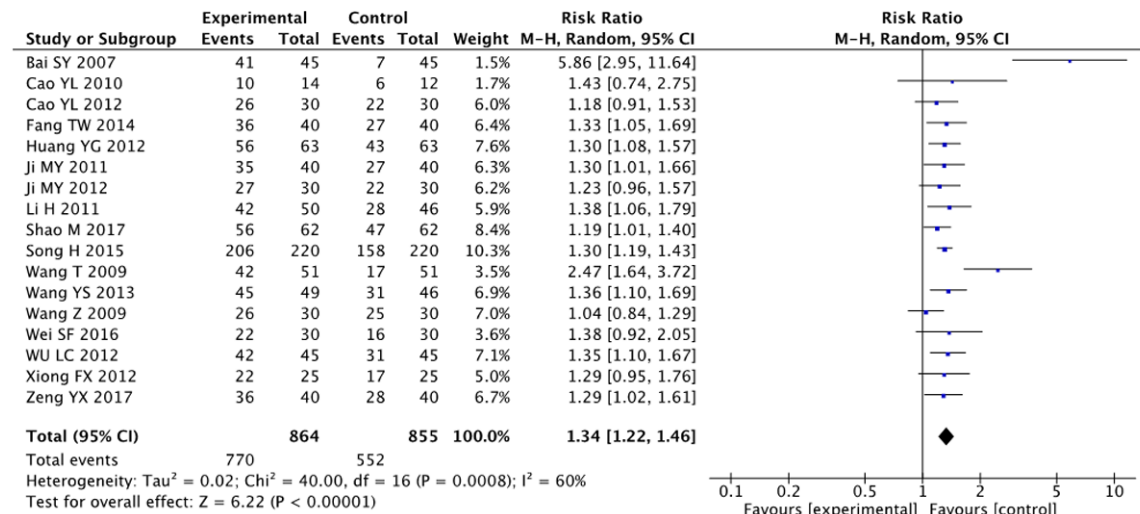


Figure 4. Meta-analysis on the effective rate of SJ capsules in the combined-drug group.

Fang TW 2014 [27], Song H 2015 [28], Wei SF 2016 [29], Zeng YX 2017 [30], and Shao M 2017 [31]. Of the 22 RCTs, 3 reported adverse events.

Therapeutic efficacy of SJ capsules on male infertility

In the single-drug group, only 1 study with 95% CI of RR was, suggesting that there was no strong evidence showing that SJ capsules were better than zinc and selenium tablets. Four articles indicated that SJ capsules were superior to Vitamin E, Clomiphene, and Bromocriptine, respectively. See Figure 3. Weighted quantitative synthesis of SJ capsules in male infertility patients was compared in the single-drug group. The merged RR was 1.70 (95% CI: 1.21-2.39), indicating that there were significant differences between SJ capsules and Western medicine on male infertility treatment. For the combined group, in 17 RCTs, only 6 RCTs 95%

CI of RR included 1. This indicates that SJ capsules, together with Western medicine, were not superior to only Western medicine in treating male infertility. See Figure 4. Weighted quantitative synthesis of SJ capsules in male infertility patients was compared in the combined-drug group. The merged RR was 1.34 (95% CI: 1.22-1.46), indicating that there were significant differences between SJ capsules and Western medicine when combining drugs to treat male infertility.

The merged RR of all included studies was 1.43 (95% IC: 1.29-1.60). See Figure 5.

Adverse events

Three of the 22 RCTs reported adverse events. Incidence of adverse events in the SJ capsules group was <5%. Li XW [15] reported that 5 patients in the treatment group developed symptoms, such as dizziness, nausea, dry mouth, and dry eyes. They were relieved and symp-

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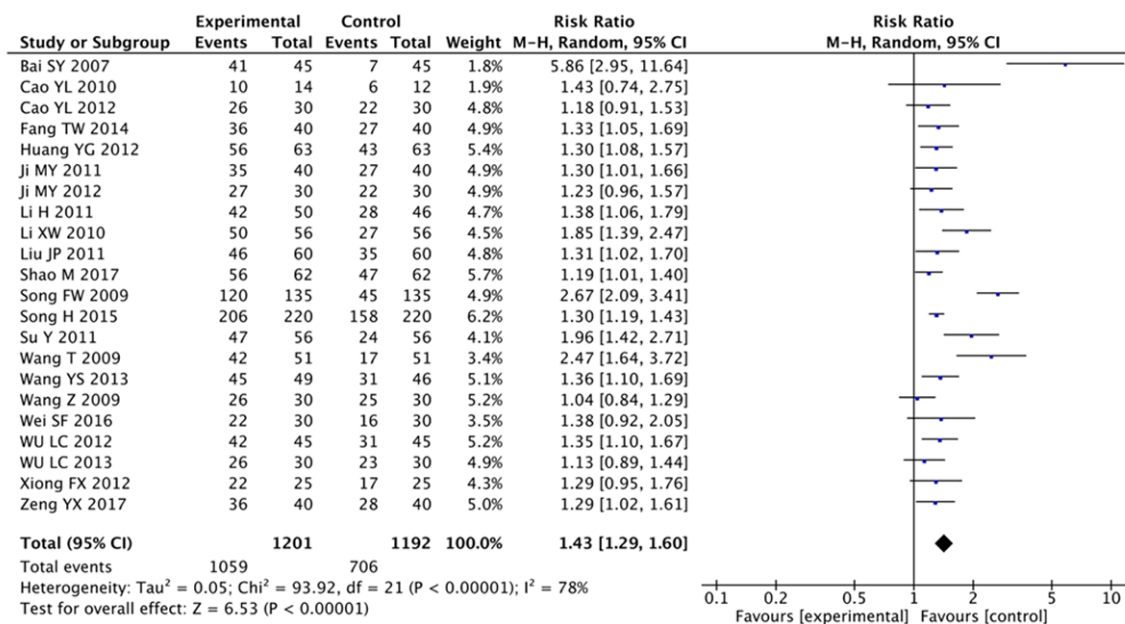


Figure 5. Meta-analysis on the effective rate of comparison of SJ capsules with Western medicine.

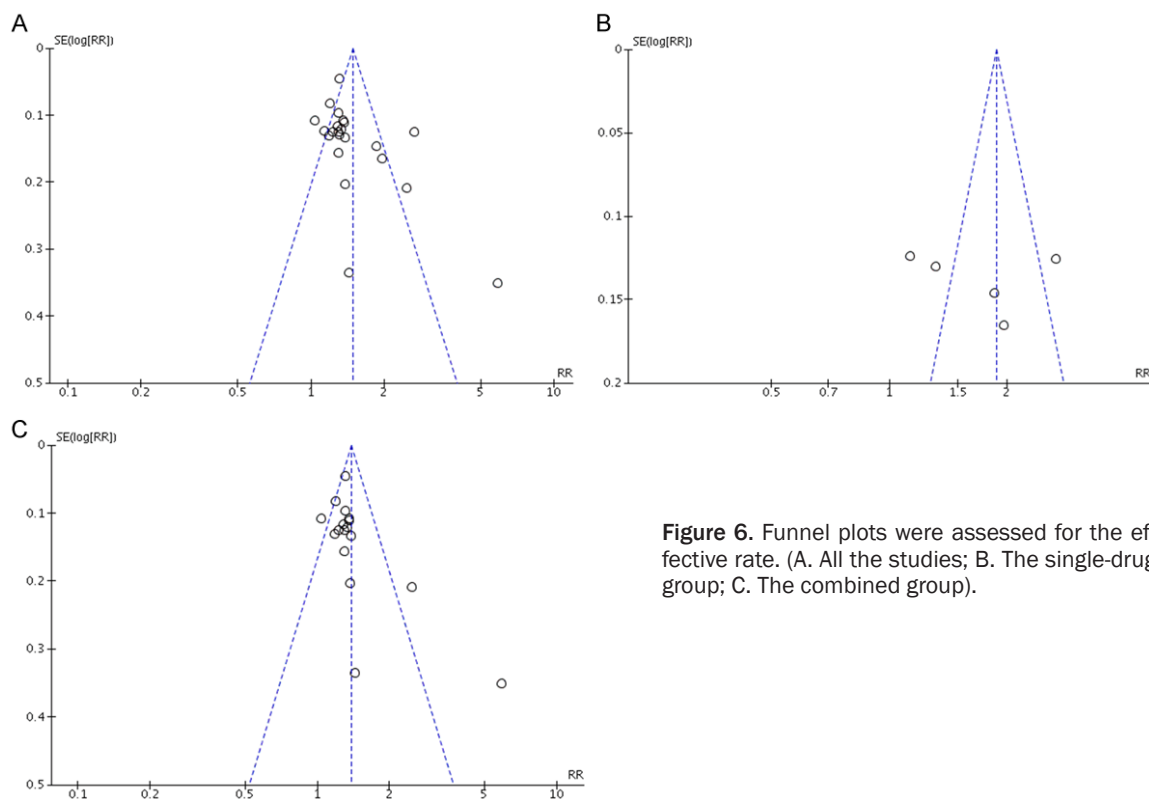


Figure 6. Funnel plots were assessed for the effective rate. (A. All the studies; B. The single-drug group; C. The combined group).

toms disappeared before the end of treatment. Two studies reported gastrointestinal reactions in 1 patient, relieved after treatment [11, 21]. Nine studies reported no adverse reactions during treatment. There was no observation of adverse effects in the remaining 10 studies.

Publication bias

Egger's test, Begg's test, and funnel plots were used to investigate publication bias. Shapes of the funnel plots appeared to be symmetrical, indicating no clear bias in either the analysis of

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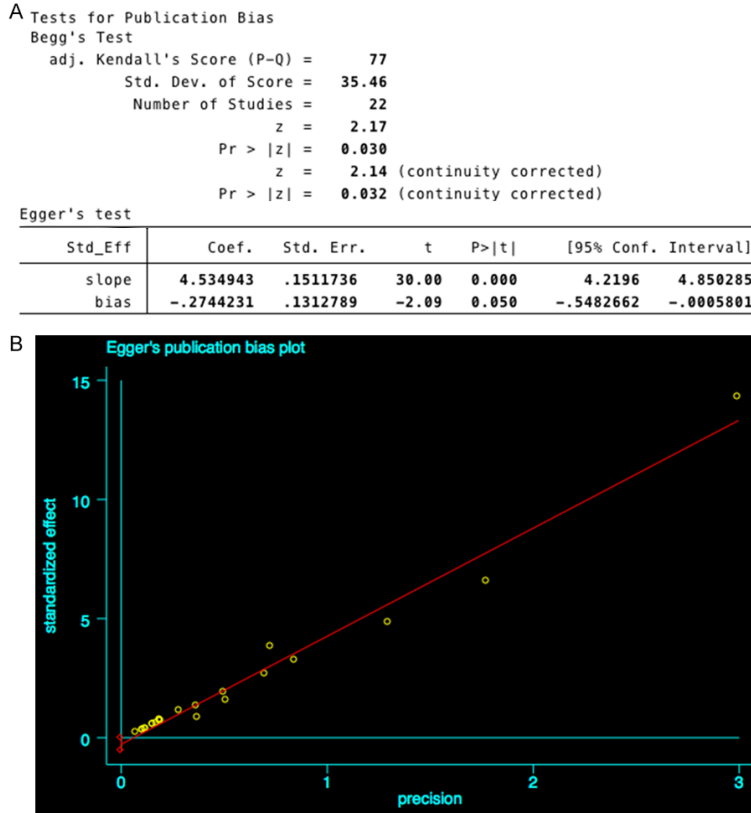


Figure 7. Egger's graph was assessed for the effective rate of all studies.

total enrolled studies (see **Figure 6A**) or comparisons between groups of SJ capsules combined with Western medicine and Western medicine alone (see **Figure 6B, 6C**). Results of Egger's tests exhibited a slight bias for overall efficacy rates of total studies ($P = 0.04$, see **Figure 7A, 7B**) and combined group studies ($P = 0.003$, see **Figure 8A, 8B**). Although the number of single-drug studies was less than 10, Egger's and Begg's tests were still conducted for effective rates. No bias was found for studies comparing efficacy rates of SJ capsules and Western medicine only ($P = 0.63$, see **Figure 9**).

Discussion

Male infertility is a common problem for couples during the childbearing period. One of the most common diseases of the male reproductive system, it has become a worldwide disease. There are many causes of male infertility. However, it still lacks effective drug therapy for treatment. Various treatments have been used in China, especially Traditional Chinese Medicine or integrated Traditional Chinese and

Western medicine. SJ capsules are one of the most effective drugs for this disease. These capsules have been confirmed by the China Food and Drug Administration (CFDA) for male infertility with azoospermia, asthenospermia, and semen unliquefaction. They are especially suitable for patients with asthenospermia.

In this study, the efficacy of treatment of male infertility with SJ capsules was evaluated with a systematic review and meta-analysis. The current study provides evidence-based choices for urologists and andrologists concerning treatment of male infertility. Twenty-two studies were selected and analyzed. Effective rates and adverse events were selected as indicators. The two groups were divided based on published papers for treatment of male infertility, as follows: 1) The single group, in which male infertility patients orally take

SJ capsules or Western medicine; and 2) The combined drugs group, in which patients took SJ capsules and Western medicine at the same time, compared with Western medicine only. In the single group and combined group, SJ capsules were shown to significantly improve sperm quality. In the single group, five studies in this cohort were poorly consistent. Thus, the I^2 was more than 50%. After sensitivity analysis, results suggest that vitamin E treatment was slightly less effective, resulting in a lower efficacy in the control group. There were greater differences in effectiveness of the two studies, resulting in higher heterogeneity. Compared with antioxidant functions of vitamin E, SJ capsules can increase the activity of antioxidant enzymes, inhibit oxidative stress, repair pathological damage of the testis and epididymis, protect against spermatogenesis, increase the number and vitality of sperm, and improve normal morphological rates of sperm [5].

Results of Begg's rank correlation test and Egger's regression test for small-study effects indicated a slight publication bias in this stu-

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A Tests for Publication Bias

Begg's Test

adj. Kendall's Score (P-Q) = -2
 Std. Dev. of Score = 24.28
 Number of Studies = 17
 z = -0.08
 Pr > |z| = 0.934
 z = 0.04 (continuity corrected)
 Pr > |z| = 0.967 (continuity corrected)

Egger's test

Std_Eff	Coef.	Std. Err.	t	P> t	[95% Conf. Interval]
slope	4.376649	.2046858	21.38	0.000	3.940371 4.812926
bias	.7895711	.2370182	3.33	0.005	.2843788 1.294763

B

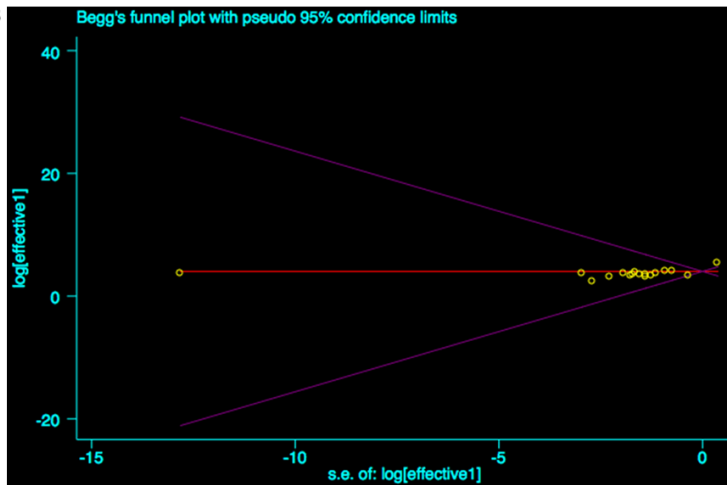


Figure 8. Begg's graph was assessed for the effective rate of the combined group.

Tests for Publication Bias

Begg's Test

adj. Kendall's Score (P-Q) = 0
 Std. Dev. of Score = 4.08
 Number of Studies = 5
 z = 0.00
 Pr > |z| = 1.000
 z = -0.24 (continuity corrected)
 Pr > |z| = 1.000 (continuity corrected)

Egger's test

Std_Eff	Coef.	Std. Err.	t	P> t	[95% Conf. Interval]
slope	3.545841	.5103273	6.95	0.006	1.921751 5.16993
bias	-.2554861	.4793146	-0.53	0.631	-1.780879 1.269907

Figure 9. Egger's test was assessed for the effective rate of the single-drug group.

dy. For this reason, the team analyzed many aspects of the situation, identifying several underlying causes: 1) Parameters in the semen and sperm selected by each study were not the same; 2) Course of treatment was inconsistent; 3) Differences in patient conditions between studies; 4) Efficacy in control groups may be different; 5) Only two studies had more than 100 cases included. The rest had small sample sizes. Other reasons include social factors and human factors. However, the objective function

and effects of SJ capsules are obvious. Although present findings suggest that patients receiving SJ capsules can significantly improve effectiveness and sperm quality, more RCTs are necessary before this treatment becomes extensively used. According to the current review, there are several recommendations for future clinical studies: 1) Studies should be randomized; 2) Subjects should be screened through more authoritative reference criteria. Rules to ensure greater consistency in patients are included; 3) The course of treatment should not be less than 3 months; 4) Single drug contrast therapy should be used if possible; 5) Blinding is recommended, ensuring more objective conclusions; and 6) All kinds of adverse events should be reported.

Conclusion

In conclusion, SJ capsules may be effective for treatment of male infertility, especially in combination with Western medicine. However, the quality of current clinical research is relatively low. Most studies combined drugs for analysis. Therefore, high-quality experimental designs, such as multi-center, randomized, parallel-controlled, and blinded methods, are necessary for future studies. Treatment of male in-

fertility with SJ capsules is worthy of further investigation.

Acknowledgements

This work was supported by the Scientific Research Fund of SiChuan Provincial Education Department (No. 17TD0014).

Disclosure of conflict of interest

None.

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