CSCanada
Cross-Cultural Communication
Vol. 11, No. 9, 2015, pp. 57-65
DOI:10.3968/7522

ISSN 1712-8358[Print]
ISSN 1923-6700[Online]
www.cscanada.net
www.cscanada.org

Transcatheter Closure vs Surgical Closure of Ventricular Septal Defect in China: A Meta-Analysis

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Supported by 2015 National Social Science Foundation of China (15BGL191).

Received 12 June 2015; accepted 18 July 2015
Published online 26 September 2015

Abstract

Objective: To compare the curative effect, safety and medical cost of transcatheter closure and surgical closure in ventricular septal defect in China，so as to provide references for treatment plans of ventricular septal defect in clinic medicine.

Methods: Chinese literature databases such as CBM, VIP, CNKI, Wan Fang and English literature databases such as PubMed, Ovid and EBSCO were searched from the date of their establishment to June 2015 for collecting the related articles, the collected articles were screened, extracted, evaluated, and analyzed by using Revman5. 3 software.

Results: 23 articles (16 Chinese articles, 7 English articles) met the inclusion criteria，transcatheter closure (TC) group included 2801 cases，surgical closure (SC) group included 3,086 cases. Meta-analysis results showed as following：(a) operation success rate：TC group was lower than SC group (*RR*=0.98, 95% CI=0.96~0.99, *P* = 0.008)；(b) operation complication rate：TC group was lower than SC group (*RR*=0.62, 95% CI=0.46~0.84, P=0.002)；(c) operation immediate residual shunt rate：TC group was lower than SC group (RR=0.69, 95% CI = 0.51~ 0.95, *P*=0.02)；(d) operation time：TC group was shorter than SC group (SMD= -2.87, 95% CI = -3.60 ~ -2.13, *P*<0.00001)；(e) length of hospital stay：TC group was shorter than SC group (SMD= -1.55, 95% *CI*=-2.14 ~ -0.95, *P*<0.00001)；(6) hospitalization expenses：TC group was higher than SC group (SMD=1.02, 95% CI=0.12~1.93, *P*=0.03).

Conclusion: TC is lower than SC in operation success rate，operation complication rate and operation immediate residual shunt rate; and TC is shorter than SC in operation time and length of hospital stay；but TC is higher than SC in the hospitalization expenses. Thus, transcatheter closure can be used as an alternative to surgical treatment in the range of indication.

Key words: Transcatheter closure; Surgical closure; Ventricular septal defect; Comparion; Meta-analysis

Zhou, T. J., Luo, Y. L. & Zhou, X. Q. (2015). Transcatheter Closure vs Surgical Closure of Ventricular Septal Defect in China: A Meta-Analysis. *Cross-Cultural Communication, 11*(9), 57-65. Available from: http//www.cscanada.net/index.php/ccc/article/view/7522
DOI: http://dx.doi.org/10.3968/7522

INTRODUCTION

Ventricular septal defect (VSD) refers to abnormal traffic between left ventricle and right ventricle due to the dysplasia or defect of the ventricular septum, and left ventricle to right ventricle blood flow [1]. VSD accounts for 20% of congenital heart disease (CHD). According to the defect site, VSD can be divided into perimembranous VSD, infundibular VSD and muscular VSD, and the perimembranous VSD is about 70% of all VSD, infundibular VSD and muscular VSD are about 30% of all VSD. VSD children appear severe symptoms which seriously affect the growth and development of them, about 9% of the children with severe VSD die within 1 years of age. Thus, once diagnosed as VSD, it should be treated immediately.

At present, the treatment strategy of VSD has natural closure, surgical closure, transcatheter closure, etc. Small VSD has the opportunity to have a natural closure, but the majority of other VSD need to be treated, while the surgical closure and transcatheter closure have become the main treatment of the VSD. In 1954, Lillehei et al

firstly treated the VSD by surgical operation; In 1988，Lock et al firstly applied interventional occluder to treat VSD; In 1990, Ren Sengen et al completed the first use of interventional occlusion for VSD in China. After several decades of clinical application, the characteristics of transcatheter closure and surgical closure were presented, surgical treatment of VSD which was ever the only treatment had been regarded as the gold standard of VSD treatment , but also had the risk of cardiopulmonary bypass, big trauma, more bleeding, longer recovery time and other shortcomings[2]. Transcatheter closure of VSD which increased the VSD treatment method had high success rate, less trauma, shorter recovery time and other advantages, but also had complex operation, high medical cost, narrow indication and other issues [3].

Under the above background, in order to provide references for the clinical optimization selection of VSD treatment programs，this study collected the literature from the date of database's establishment to June 2015 on the treatment of VSD by transcatheter closure and surgical closure, used meta-analysis method, compared each advantages and disadvantages between transcatheter closure and surgical closure in the treatment of VSD.

1 MATERIAL AND METHODS

1.1 Inclusion and Exclusion Criteria

1.1.1 Inclusion Criteria

(a) Study design: non randomized controlled trials or randomized controlled trials; (b) Study object: patients were diagnosed as VSD by iconography; patients with various types of VSD; patients were suitable for transcatheter closure or surgical operation; (c)intervention measures: the experimental group was treated by transcatheter closure, the control group was treated by surgical closure; (d) indicator measurement: ① operation success rate; ②operation complication rate;③operation immediate residual shunt rate; ④ operation time; ⑤ length of hospital stay; ⑥ hospitalization expenses.

1.1.2 Exclusion Criteria

(a) non controlled trial; (b) wrong research data or method; (c) small sample size.

1.2 Literature-Search Strategy

(a)Ventricular septal defect (VSD), transcatheter closure and surgical operation, compare, etc as key words were searched in Chinese database such as Chinese Biomedical Literature (CBM), CNKI, VIP, WanFang, et.c; ventricular septal defect (VSD), transcatheter closure and surgical operation, compare, etc as key words were searched in English database such as PubMed, EBSCO and Ovid, etc.;

(b) retrieval time: from the date of their establishment to June 2015.

1.3 Data Extraction and Quality Assessment

Data extraction was independently conducted by 2 persons, the contents were recorded as follows: first author, publication year, intervention measures, the number of cases, gender, age, weight, VSD size, and indicator measurement. MINORS (total score of 24 points) which was recommended for non randomized controlled study was a quality evaluation tool[4].

1.4 Statistical Analysis

Revman5.3 was adopted for the meta-analysis, risk ratio (*RR*) was used as effect for the binary data, standard mean difference (SMD) was used as effect for continuous data. If the Chi square test > 0.10, it meant no heterogeneity, fixed effect model was used; if the Chi square test $P <$ 0.10, it meant heterogeneity, At the same time, if Q test I^2<50%, it showed little heterogeneity, the fixed effect model was used, if Q test I^2>50%, we analyzed source of heterogeneity，a random effect model was selected; we chose Begger method to assess the publication bias.

2 RESULTS

2.1 Search Results and Study Characteristics

Literature retrieval process was shown in Figure 1.

The results of the literature excerpt were shown in Table 1.

2.2 Data Quality

Literature quality evaluation results were shown in Table 2.

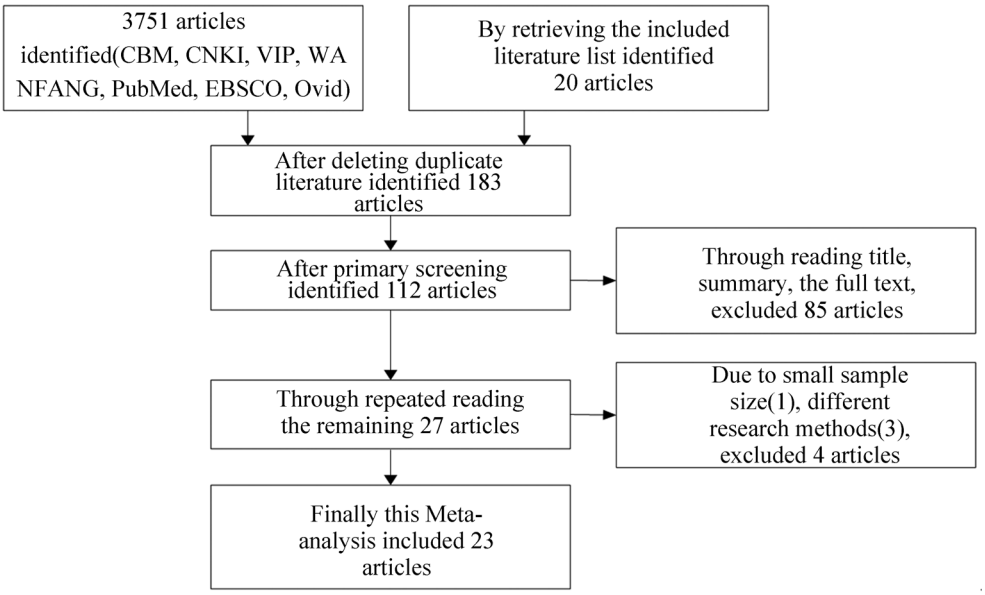

Figure 1
Flow Chart of Literature Retrieval

Table 1
Information of Literature Excerpt

No.	First author	Year	Gro-up	N	Sex (M/F)	Age (year)	Weight (kg)	VSD size (mm)	I M
1	Hu h-b [5]	2004	TC	45	22/23	17.1	44.8	5.0±1.2	①②③
			SC	45	21/24	15.1	38.6	5.1±1.4	
2	Sun y [6]	2004	TC	38	17/21	12.7±13.2		5.8±2.5	①②⑤⑥
			SC	86	39/47	9.6±8.7		7.7±6.0	
3	Dai z-x[7]	2005	TC	243	96/147	8±11		8.4±6.1	①②③④⑤
			SC	215	81/134	9±10		8.5±5.0	
4	Ou x[8]	2005	TC	48	33/15	6.5±3.5	21.7±10.0	3.9±1.7	①②③④⑤
			SC	73	51/22	6.5±3.5	19.6±9.4	7.4±4.1	
5	Zhang h[91]	2006	TC	174	90/84	8.6±0.4	22.0±9.5	5.2±1.9	①②⑤
			SC	78	37/41	9.1±0.6	20±10	13.1±6.5	
6	Cheng x-m [10]	2006	TC	73	24/49	7.5		4.8	①②
			SC	48	10/38	4.4		8.2	
7	Xiao y-q[11]	2008	TC	20	9/11	11.2±6.8		5.6±1.3	①②③⑤⑥
			SC	20	11/9	12.0±7.6		6.1±1.8	
8	Zhu y-m[12]	2008	TC	40	20/20	10.1±1.3	44.8±3.5	7.6±3.2	①②③
			SC	40	20/20	10.1±1.2	44.8±3.6	7.6±3.1	
9	Wang s-q[13]	2008	TC	87	46/41	16.3±7.2		4.8±1.3	①②③⑤⑥
			SC	62	39/23	18.4±9.2		7.7±6.8	
10	Wu d-k[14]	2009	TC	30	17/13	10.5±6.2		4.0±0.6	①②⑤⑥
			SC	30	15/15	9.0±7.5		7.8±0.7	
11	Zheng q-j[15]	2009	TC	852	481/371	2.5~15.5	11~63.5	3~12	①②③⑤
			SC	1326	712/614	2.8~52.5	11.5~68	3~36	
12	Xia s-l[16]	2009	TC	114	67/47	6.3±3.4	21.4±8.6	5.5±1.8	①②③④⑤
			SC	62	41/21	3.9±3.5	14.9±8.8	9.3±4.4	
13	Zhou n[17]	2010	TC	33	17/16	10.5±8.0	32.8±13.8	6.3±2.0	①②③④⑤
			SC	34	20/14	5.9±4.2	19.0±10.1	11.8±5.6	

To be continued

Continued

No.	First author	Year	Gro-up	N	Sex (M/F)	Age (year)	Weight (kg)	VSD size (mm)	I M
14	Chen y-x[18]	2010	TC	60	29/31	10.6±11.1		5.6±2.4	①②③⑤⑥
			SC	58	28/30	8.3±7.9		7.4±6.0	
15	Liu S-x[19]	2012	TC	157	64/93	18.1±15.1		4.1±1.4	①②③④⑤⑥
			SC	188	96/92	7.5±9.4		6.3±4.1	
16	Zhang g-c[20]	2013	TC	82	32/50	21.2±5.3	49.6±9.5	5.2±1.3	①②③④⑤⑥
			SC	56	26/30	20.1±6.9	48.5±9.9	5.5±1.6	
17	Zeng x-g[21]	2013	TC	61					①②⑤⑥
			SC	61					
18	Xu x-l[22]	2014	TC	200	108/92	10.9±6.5	27.6±6.3	6.8±3.9	①②③④
			SC	105	54/51	9.9±7.5	26.4±6.0	6.5±2.8	
19	Long k[23]	2014	TC	52	32/20	21.2±5.3	49.6±9.4		①②③
			SC	50	20/30	20.1±6.9	48.5±9.9		
20	Chen z-y[24]	2014	TC	81	37/44	16±11.7	41.3±18.5	4.1±1.2	①②③④⑤⑥
			SC	115	60/55	3.8±2.4	15.3±5.3	4.3±1.3	
21	Hu y-j[25]	2014	TC	30	15/15	5.3±3.6	18.1±10.4	5.1±2.2	①②③④⑤⑥
			SC	96	42/54	4.4±3.0	16.4±6.1	4.2±1.8	
22	Yang j[26]	2014	TC	101	50/51	5.5±2.6	22.1±13.8	5.2±6.1	①②③④⑤⑥
			SC	99	61/38	5.8±2.4	20.5±12.4	5.9±5.3	
23	Luo y-k[27]	2015	TC	172	101/71	3.7±5.5	14.9±13.0	4.5±1.6	①②③④⑤⑥
			SC	139	69/70	3.7±2.4	15.9±5.3	4.6±2.4	

Note. TC= transcatheter closure, SC= surgical closure. IM= indicator measurement.

Table 2
Quality Evaluation of Literature

No.	First author	1	2	3	4	5	6	7	8	9	10	11	12	Scores
1	Hu h-b	2	2	2	2	0	2	2	0	2	2	1	2	19
2	Sun y	2	2	2	2	0	1	2	0	2	2	2	2	19
3	Dai z-x	2	2	2	2	0	1	2	0	2	2	2	2	19
4	Ou x	2	2	2	2	0	1	2	0	2	2	2	2	19
5	Zhang h	2	2	2	2	0	1	1	0	2	2	2	1	17
6	Cheng x-m	2	2	2	2	0	2	2	0	2	2	2	2	20
7	Xiao y-q	2	2	2	2	0	1	2	0	2	1	2	2	18
8	Zhu y-m	2	2	2	2	0	2	2	0	2	1	2	2	19
9	Wang s-q	2	2	2	2	0	1	2	0	2	1	2	2	18
10	Wu d-k	2	2	2	2	0	2	2	0	2	1	1	2	18
11	Zheng q-j	2	2	2	2	0	2	1	0	2	2	2	2	19
12	Xia s-l	2	2	2	2	0	2	2	0	2	1	1	2	18
13	Zhou n	2	2	2	2	0	2	2	0	2	1	1	2	18
14	Chen y-x	2	2	2	2	0	2	2	0	2	1	2	2	19
15	Liu s-x	2	2	2	2	0	2	2	0	2	2	2	2	20
16	Zhang g-c	2	2	2	2	0	2	2	0	2	1	2	2	19
17	Zeng x-g	2	2	2	2	0	2	2	0	2	1	2	2	19
18	Xu x-l	2	2	2	2	0	2	2	0	2	1	2	2	19
19	Long k	2	2	2	2	0	2	2	0	2	1	1	2	18
20	Chen z-y	2	2	2	2	0	2	2	0	2	2	2	2	20
21	Hu y-j	2	2	2	2	0	2	2	0	2	2	2	2	20
22	Yang j	2	2	2	2	0	2	2	2	2	2	2	2	22
23	Luo y-k	2	2	2	2	0	2	2	0	2	2	2	2	20

Note. 1. a clearly stated aim; 2. inclusion of consecutive patients; 3. prospective collection of data; 4. endpoints appropriate to the aim of the study; 5.unbiased assessment of the study endpoint; 6. follow-up period appropriate to the aim of the study; 7. loss to follow up less than 5%; 8. prospective calculation of the study size; 9. an adequate control group; 10. contemporary groups; 11. baseline equivalence of groups; 12. adequate statistical analyses. The items were scored 0(not reported),1(reported but inadequate) or 2 (reported and adequate).

2.3 Meta-Analysis Results

2.3.1 Operation Success Rate

References [5-27] reported operation success rate in two groups, after heterogeneous test (P <0.00001, I^2=77%), it showed heterogeneity between the studies, the random effect model was used to merge, meta-analysis results showed that: the TC group was lower than that in the SC group (RR=0.98, 95% CI=0.96~0.99, P=0.008). As shown in Figure 2. There was no publication bias by Begger method for quantitative assessment of publication bias (P=0.170).

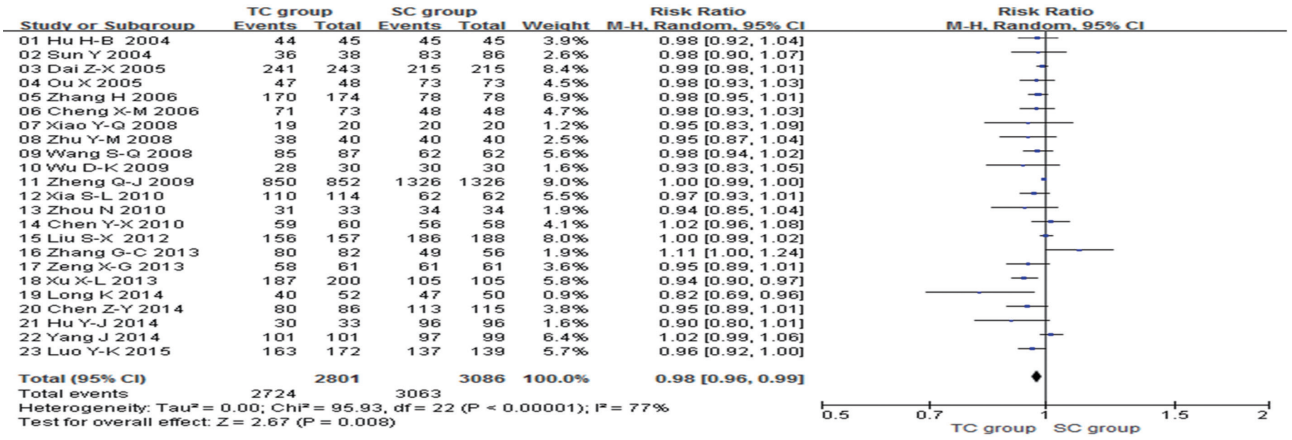

Figure 2
Forest Plot of Operation Success Rate

2.3.2 Operation Complication Rate

References[5-27] reported operation complication rate in two groups, after heterogeneous test (P <0.00001, I^2=77%), it showed heterogeneity between the studies, the random effect model was used to merge, meta-analysis results showed that: the TC group was lower than that in the SC group (RR=0.62, 95%CI=0.46~0.84, P=0.002). As shown in Figure 3. There was no publication bias by Begger method for quantitative assessment of publication bias (P=0.958).

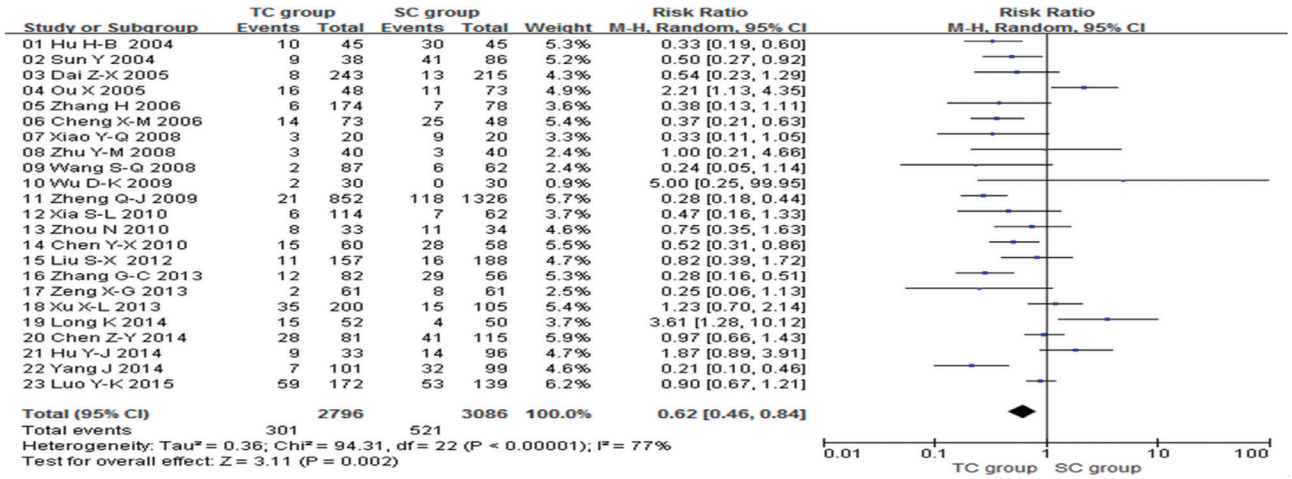

Figure 3
Forest Plot of Operation Complication Rate

2.3.3 Operation Immediate Residual Shunt Rate

References[5, 7-8, 11-13, 15-20, 22-27] reported operation immediate residual shunt rate in two groups, after heterogeneous test (P =0.40, I^2=5%), it showed no heterogeneity between the studies, the fixed effect model was used to merge, meta-analysis results showed that: the TC group was lower than that in the SC group (RR=0.69, 95% CI=0.51~0.95, P=0.02). As shown in Figure 4. There was no publication bias by Begger method for quantitative assessment of publication bias (P=0.820).

2.3.4 Operation Time

References[8-9,16-17,19-20, 22, 24-27] reported operation time in two groups, after heterogeneous test (P <0.0001, I^2=98%), it showed heterogeneity between the studies, the random effect model was used to merge, meta-analysis results showed that: the TC group was shorter than that in the SC group (SMD=-2.87, 95% CI=-3.60~-2.13, P<0.00001). As shown in Figure 5. There was no publication bias by Begger method for quantitative assessment of publication bias (P=0.087).

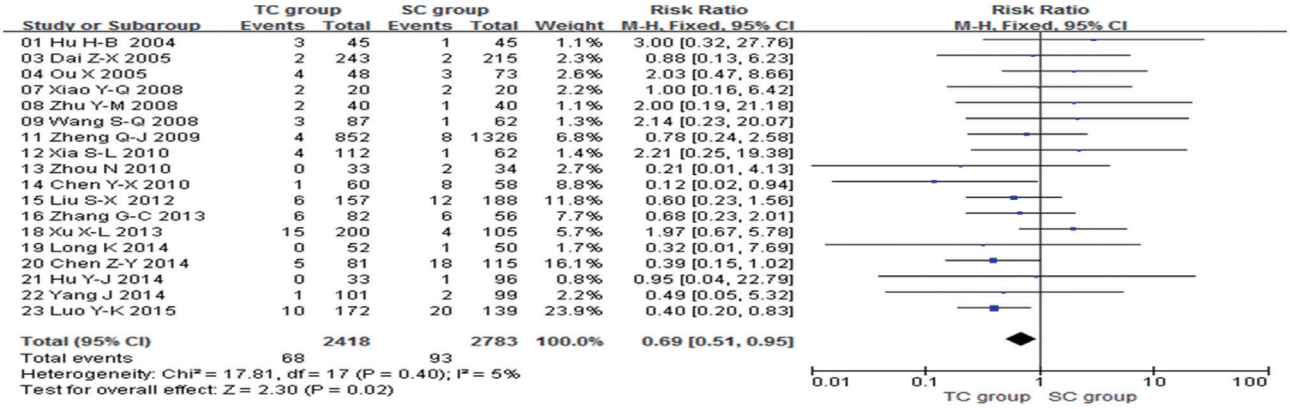

Figure 4
Forest Plot of Operation Immediate Residual Shunt Rate

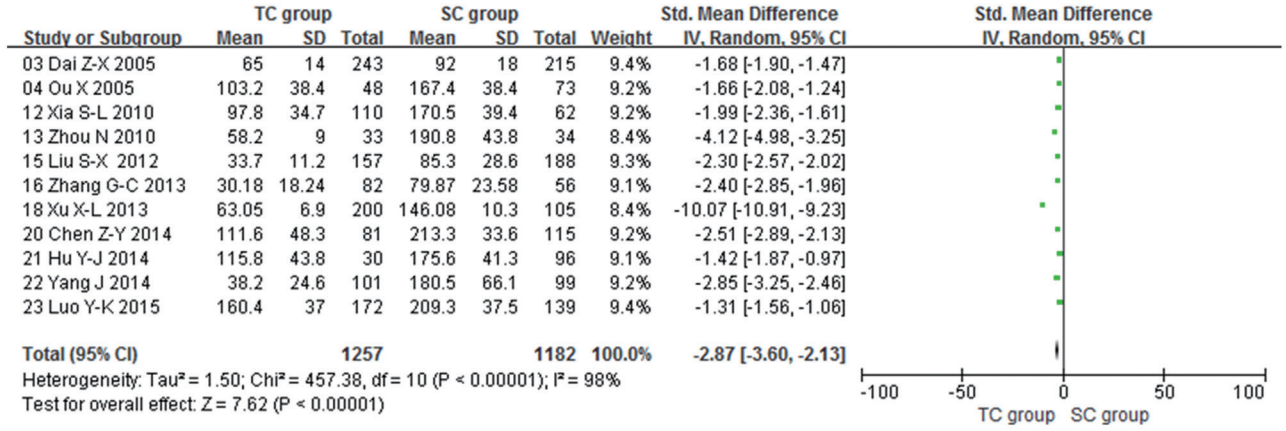

Figure 5
Forest Plot of Operation Time

2.3.5 Length of Hospital Stay

References[6-9, 11,13-21, 24-27] reported length of hospital stay in two groups, after heterogeneous test (P <0.0001, I^2=99%), it showed heterogeneity between the studies, the random effect model was used to merge, meta-analysis results showed that: the TC group was shorter than that in the SC group (SMD=-1.55, 95% CI=-2.14~-0.95, P<0.00001). As shown in Figure 6. There was no publication bias by Begger method for quantitative assessment of publication bias (P=0.544).

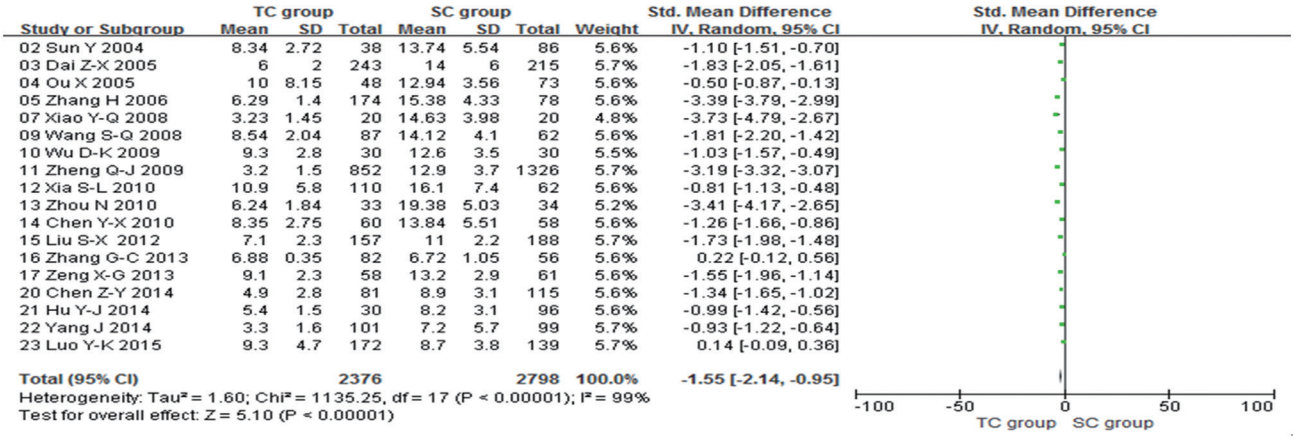

Figure 6
Forest Plot Of Length Of Hospital Stay

3.3.6 Hospitalization Expenses

References[6, 11, 13-14, 18-21, 24-27] reported hospitalization expenses in two groups, after heterogeneous test (P <0.0001, I^2=99%), it showed heterogeneity between the studies, the random effect model was used to merge, meta-analysis results showed

that: the TC group was higher than SC group (SMD=1.02, 95% CI=0.12~1.93, *P*=0.03). As shown in Figure 7. There was publication bias by Begger method for quantitative assessment of publication bias (*P*=0.034).

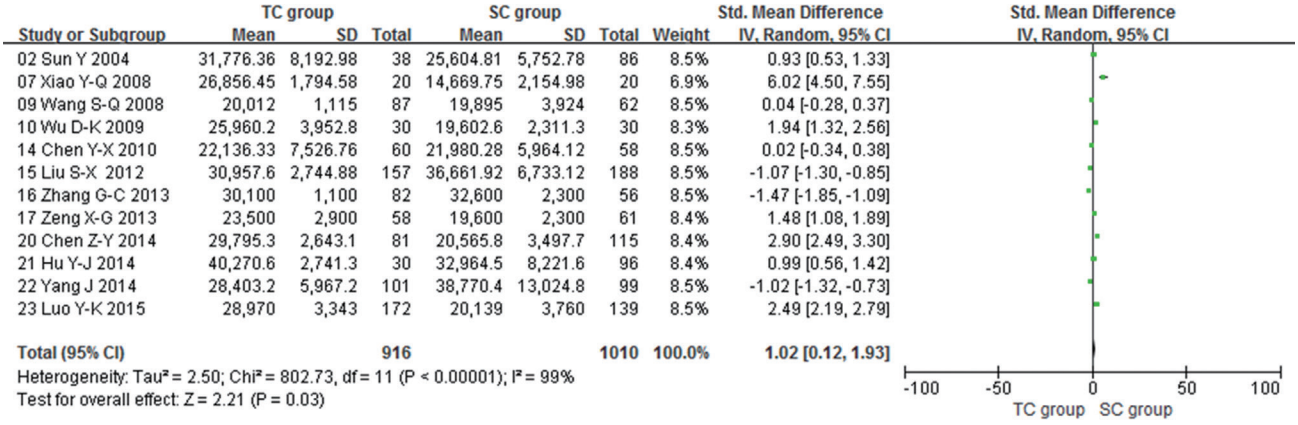

Figure 7
Forest plot of Hospitalization Expenses

2.3.7 Sensitivity Analysis

When we carried out sensitivity analysis of operation success rate, operation complication rate, operation time, length of hospital stay and hospitalization expenses by excluding each of the studies, little change results showed that the stability were good; however, result of hospitalization expenses changed a lot, showed that the stability was poor.

DISCUSSION

After 60 years of clinical application, surgical treatment had a unique advantage in young children, low birth weight, large defect and so on ; However, surgical operation required cardiopulmonary bypass, which increased the risk of operation, surgical operation need open chest operation on the patient's body，which also caused great trauma, scar and increased the psychological burden of patients；surgical operation possibly need blood transfusion, which increased the risk of exposure to blood products；surgical operation led to more postoperative complications，which caused poor curative effect. Therefore, the treatment method of small trauma, low risk, good curative effect was expected by the doctors and patients.

The emergence of transcatheter closure had attracted people's attention. At first, due to the complex operation and poor curative effect, interventional therapy could not be widely used in clinical medicine. In 2002, Amplatzer developed a perimembranous occluder, which promoted the application of interventional occlusion[28]. At the same time, with the development and application of domestic VSD occluder, VSD occluder was widely used in domestic hospital. At present, according to the shape and size of the VSD，interventional treatment should choose the appropriate occluder for transcatheter closure[29]，membranous VSD and muscular VSD were suitable for transcatheter closure. Intervention closure had advantages of low trauma, quick recovery and less complication, attracted the doctors and patients, and became the first choice of VSD patients in the indication of transcatheter closure.

This study showed as following: (a) operation success rate: TC group was lower than that in the SC group (*RR*=0.98, 95% CI=0.96~0.99, *P* = 0.008), because of the wide open heart surgery, the operation success rate was higher; (b) operation complication rate: TC group was lower than that in the SC group (*RR*=0.62, 95% CI=0.46~0.84, *P*=0.002), because of the large trauma and bleeding caused by the surgical operation, surgical operation had more complications; (c) operation immediate residual shunt rate: TC group was lower than that in SC group (*RR*=0.69, 95% CI=0.51~0.95, *P*=0.02), in the long time of postoperative follow-up, most residual shunt cases disappeared in the two groups; (d) operation time: TC group was shorter than that in SC group (SMD=-2.87, 95% CI=-3.60~-2.13, *P*<0.00001), due to the development of interventional occlusion, interventional operation under echocardiography guidance was simple; (e) length of hospital stay: TC group was shorter than SC group (SMD=-1.55, 95% CI=-2.14~-0.95, *P*< 0.00001), surgical operation need to enter the ICU to observe and treat; (f) hospitalization expenses: TC group was higher than SC group (SMD=1.02, 95% CI=0.12~1.93, *P*=0.03), due to the expensive occluder and transmission equipment, hospitalization expenses of interventional occlusion was higher.

In summary, this study included 23 articles (16 Chinese articles, 7 English articles), transcatheter closure group had 2801 cases, surgical operation group had 3086 cases. Meta-analysis was used to analyze the 6 outcome measures of VSD in this study. The operation success rate, operation complication rate and operation immediate residual shunt rate of interventional occlusion were lower than that of surgery; operation time and length of hospital stay in interventional occlusion were shorter than that of

surgery；but interventional occlusion was higher than that of surgery in the hospitalization expenses. Thus, transcatheter closure can be used as an alternative to surgical treatment in the range of indication.

Study limitation: First, this study could not include the foreign research literature on the VSD, can only reflect the domestic research results for VSD, can not reflect the comprehensive results of the VSD studies both at home and abroad. Second, this study included the literature for non randomized controlled trials, if randomized controlled trials was included , the research results will be strengthened. Third, the number of the literature and the quality of the literature were limited, if more and better research literature can be included, it can make the meta-analysis results more accurate and reliable.

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