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MICROSURGICAL AND VARICOCELECTOMY COMPARISON WITH AND WITHOUT TESTICULAR DELIVERY FOR TREATMENT OF VARICOCELE: A RANDOMIZE CONTROL TRIAL

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ABSTRACT

Purpose: Varicocele is a common type of male genital disease and can occur in men of any age, especially young people. Clinically venous enlargement or varicocele are found in about 15% of the general male population, up to 35% of men with primary fertility, and 75% of men with secondary fertility dysfunction. Varicoceles are known to be the most common cause of male infertility and can be corrected surgically, but the exact mechanism of sperm formation caused by varicocele-induced impairment remains controversial. Most men with varicocele are asymptomatic and infertile, with only 15% – 20% suffering from physical discomfort or other fertility-related problems. With therefore systematically evaluated the RCTs published together and summarized evidence evaluating the benefits of testicular delivery and ligation of gubernacular vein in microsurgical varicocelectomy.

Methodology: Comprehensive electronic search using the keywords "microsurgical varicocelectomy", "gubernacular vein", "testicular delivery", "infertility" and "varicocele" was done in databases of Cochrane, PubMed, Embase, CINAHL and Web of Science databases. English language was used to search databases. Some studies were taken from studies references.

Result: Two studies reported grade II and III of varicoceles in patients that participated in the study. Overall sperm count in microsurgical resection with testicular delivery compared to microsurgical resection without testicular delivery, increased significantly (SMD = 0.23, 95% CI = 0.07-0.39, p =<.05), but sperm motility, sperm concentration and gradual increase have no difference in between the two microsurgical methods (p> 0.05).

Conclusion: In conclusion, as a result of this systematic review and meta-analysis, compared with microsurgical varicocelectomy without testicular delivery, delivery of the testicles during microsurgical varicocelectomy to further to further ligate the gonadal veins leads to epidydemo orchitis and oedema, and longer surgery. In addition, testicular delivery may not improve parameters of sperm, serum testosterone, and incidence of varicose veins, wound inflammation and spontaneous pregnancy compared to non-delivered testicles. However, a higher level of research is needed to determine if testicular delivery is an important surgery in microsurgical venous ligation.

Keywords: *Gubernacular veins, meta-analysis, testicular delivery, varicocele, varicocelectomy*

Introduction

Varicocele or dilatation of the scrotal veins is one of the most commonly occurring urological disease (1). Varicocele (VC) is the dilatation and tortuosity of the pampaniform plexus that drains the testicles (2). VC is a common type of male genital disease and can occur in men of any age, especially young people (3). It affects roughly 15% of the overall male population, up to 35% of men with primary infertility and up to 75% of men with secondary infertility. Varicocele is known to be the most common cause of male infertility which can be corrected surgically, but the exact mechanism of sperm damage caused by varicocele remains controversial. Most men with varicocele are asymptomatic with only 15% –20% suffering from physical discomfort and fertility-related problems (4).

The adverse effects of varicocele on sperm production are well known and can be seen in 21% – 41% of men with primary fertility and in 75–81% of men diagnosed with secondary fertility dysfunction (5, 6). If left untreated, this condition can lead to damage to the sperm, dysfunction of Leydig cells and decrease in testicular volume. (7). Open method, minimally invasive resection, MSV or microsurgical sub-inguinal/ inguinal varicocelectomy and laparoscopic ligation are some of the most popular surgical procedures for varicocele. Several studies have shown that MSV has many advantages over its counter parts, such as increased pregnancy rates, shorter hospitalizations, reduced costs, reduced anesthetic effects, and reduced complications (8, 9 - 12). Surgery is a viable treatment option for VC, since it can improve sperm parameters, serum testosterone levels, and pregnancy rates. (13, 14). Conventional open surgery, laparoscopic resection and microsurgical resection are all surgical options for VC. (15, 13, 16). Compared to open surgeries and laparoscopy, MSV can help operators specifically identify testicular arteries and lymph vessels. Thus, MSV can reduce the likelihood of arterial injury and spare lymphatics and thus reduce postoperative complications. Several studies have shown that the main cause of recurrence of varicocele after surgery is the presence of veins of the gubernaculum (17). In microsurgical varicocelectomy delivery of the testicles can properly ligate the gubernacular and other small veins (18). There is still some ambiguity regarding the effects on sperm production, complications and recurrence of MSV with testicular delivery (TD) and ligation of gubernacular vein. In recent years, many studies have been done on the role of testicular delivery in microsurgical varicocelectomy. (19, 20, 21, 22, 23, 24, 25, 26).

However, the results of these studies are inconsistent and contradictory, and the lack of sample size in the study undermines the validity of the evidence. The question of whether the patient should undergo surgery for microsurgical varicocelectomy remains controversial. We therefore systematically evaluated the RCTs published together and summarized evidence evaluating the benefits of testicular delivery and ligation of gubernacular vein in microsurgical varicocelectomy.

Literature search methodology

Comprehensive electronic search using the keywords "microsurgical varicocelectomy", "gubernacular vein", "testicular delivery", "infertility" and "varicocele" was done in databases of Cochrane, PubMed, Embase, CINAHL and Web of Science databases. English language was used to search databases. Some studies were taken from studies references.

INCLUSION AND EXCLUSION CRITERIA

The eligibility criteria for this systematic review and meta-analysis was following for all the selected articles:

(a) Study design: All randomized control trails (RCT) articles were selected for meta-analysis which mentioned treatment of enlarged scrotal veins or varicocele by comparing two methods of microsurgical varicocelectomy with and without testicular delivery (TD).

(B) Participants: Patients with varicoceles, including adults or teenagers, who underwent microsurgical varicocelectomy with and without testicular delivery (TD). According to a physical examination, the severity of enlargement of vein of testicles veins is (1) Level I: Only during Valsalva maneuver, veins are palpable (2) Level II: both visible and palpable at Valsalva but not visible at rest, (3) Level III: visible and palpable at rest.

(C) Type of intervention: For the treatment of varicocele, microsurgical resection with testicular delivery and banding of gubernacular veins was compared to microsurgical varicocelectomy without testicular delivery.

(D) Outcome of the measurement type: time of action, hospitalization, increase in serum testosterone, increase in sperm parameters after surgery (sperm motility, sperm concentration, total sperm count, abnormal sperm), postoperative complications (scrotal edema, epidermitis, wound infection and recurrence of varicose veins) were find out in meta-analysis. The sperm analysis findings are in accordance with the World Health Organization's (WHO) fifth version of sperm analysis evaluation requirements (World Health Organization, 2010).

In addition, the criteria for exclusivity are: (a) All the studies other than RCT, (b) duplications, (c) data are not available.

Bias assessment and evidence quality assessment

Biasedness of the registered RCT was assessed using the Cochrane Risk of Bias tool (version 5.1.0). (A) selection deviation (random production), (b) selection deviation (randomization), (c) performance deviation, (d) identification deviation, (e) friction deviation, (f) reporting deviation, (g) other deviations. The 9-point scale assesses bias in three areas: subject selection, contrast between groups, and exposure or result certainty. Studies with a total score of 7 or higher in the NOS are considered qualitative studies.

Statistical analysis was made for the final comparison by analyzing the relative ratio and the standard mean difference having the confidence interval 95% (CI). Fixed effect model (FEM) and random effect model (REM) were applied for RR and SMD evaluation. Heterogeneity is measured by the Cochrane Q test and I2 values. If the P value of the Cochrane Q test is greater than 0.05, then FEM is used (Mantel and Haenszel, 1959). If not fulfilling this criterion than REM is used (Dersimonian and Laird, 1986). In addition, levels of varicocele were stratified and further analyzed for consideration of the diversity of varicocele levels. Then, using sensitivity analysis, each study was in turn deleted to confirm its stability and reliability. The Egger test and the Begg funnel map were both used to determine a major bias to set the p value for the Begg funnel chart or the Egger test to 0.05 will be considered negative bias of publication.

Sample size collection

SPSS version 22 was used for the analysis. Meta-analysis of the study was done through the Cochrane Collaboration, 2014).

RESULTS

Eligible studies

The researchers identified 47 articles that were relevant. In these related study articles, 29 different articles were received without recurrence. Subsequently, 11 articles were removed due to titles or abstracts in accordance with our eligibility and our exclusive criteria. Full text analysis of the remaining 18 studies was performed. After this analysis, 13 studies were removed and 5 RCTs were preserved (Study by Allameh et al., Hou et al., Li et al., Nie et al., Spinelli et al.in 2018, 2015, 2017, 2017, and 2016 respectively). The literature search process and the detailed filtering steps are shown in Figure 1. The meta-analysis finally included 753 participants, including 367 patients who underwent microsurgical resection with testicular delivery and 386 who undergo microsurgery without testicular delivery. In 5 RCTs studies, all patients who underwent microscopic vascular resection, gubernacular veins were banded simultaneously in all patients of testicular delivery. Table 1 lists the main characteristics of the articles listed.

Table 01: Sample size Patients age (Mean ± SD) Microsurgical Varicocele

Microsurgical Varicocele											
First author	Publica-tion year	Study design	Varicocele-ctomy with TD	Varicocele-ctomy without TD	Surgical approach	Follow-up appointment	Varicocele grade	With TD group	Without TD group	Pt-test	Ligation of guber-nacular veins
Yi Hou	2015	RCT	50	50	Sub inguinal	3 months	I-III	27.94 ± 3.46	28.32 ± 3.89	>0.05	Yes
F. Allameh	2018	RCT	208	208	Inguinal	6 months after surgery	III	25.9 ± 4.6	27.3 ± 6.1	>0.05	Yes
Claudio Spinelli	2015	RCT	35	35	Inguinal	1 year after surgery	NA	14.6	14.4	>0.05	Yes
Huan Nie	2017	RCT	20	20	Sub inguinal	6 months after surgery	NA	26.7	26.7	>0.05	Yes
Xueqiong Li	2017	RCT	54	73	Sub inguinal	3 months after surgery	II-III	24.7 ± 5.9	27.6 ± 8.2	>0.05	Yes

Bias assessment and evidence quality assessment

Table 1 showed the risks of RCT bias assessment. Two of the included proven random sequence methods. In these five studies there is lack of attrition bias and no concealment of assignment in most studies.

Meta-analysis results (Operation time and hospital stay)

While searching we found that two studies (Hou et al., 2015; Li et al., 2017) reported data on time of surgery and hospitalization. Collected SMD showed that in comparison between microsurgical removal of enlarged scrotum vein with and without testicular delivery, microsurgical vascular resection with testicular delivery required longer surgical time compared with microsurgery without testicular delivery (SMD = 1.14, 95% CI = 0.41-1.87, p = 0.002) shown in Table 2. There wasn't any significant difference during hospitalization (SMD = 0.22, 95% CI = 0.04 to 0.48, p = 0.101) (Table 2).

Table 02: Meta-analysis results

Outcomes	I2 (%)	Heterogeneity	Effect model	SMD (95% CI)	p-value	Begg's test p
Operation time (min)	90.2%	0.000	Random model	1.14 (0.41,1.87)	0.002	0.734
Hospital stay (day)	0.0%	0.357	Fixed model	0.22 (−0.04, 0.48)	0.101	0.602
Improvement of serum testosterone (ng/dl)	97.7%	0.000	Random model	−1.54 (−4.20, 1.13)	0.258	1.000
Decrease of abnormal sperm (%)	96.9%	0.000	Random model	0.83 (−1.06, 2.72)	0.390	1.000
Improvement of sperm viability (%)	87.4%	0.005	Random model	0.33 (−0.39, 1.04)	0.367	0.317
Improvement of sperm concentration (106/ml)	94.3%	0.000	Random model	−0.35 (−1.08, 0.37)	0.558	1.000

Varicocele occurrence and complications

To find the relationship between testicular delivery and complications, we also analyzed major postoperative complications related to varicocele, orchiepididymitis, edema of the scrotum, and wound inflammation. There was no variance in the occurrence of varicocele between the two varicocelectomy (RR = 0.55, 95% CI = 0.07–4.13, p = 0.558) (Table 3) and wound infection (RR = 0.41, 95% CI = 0.07–2.43, p = 0.328). Yet, our results show more testicular oedema (RR = 4.36, 95% CI = 1.12-16.99, p = 0.034) (Table 3) and scrotal edema (RR = 4.25, 95%) in microsurgical varicocele with testicular delivery, compared to microsurgical varicocele without testicular delivery after surgery (Table 3).

Table 03: Varicocele occurrence and complications

Outcomes	I2 (%)	Heterogeneity	Effect model	SMD (95% CI)	p-value	Begg's test p
Varicocele recurrence	74.5	0.02	Random model	0.55 (0.07, 4.13)	0.558	0.602
Orchiepididymitis	0.0	0.955	Fixed model	4.36 (1.12, 16.99)	0.034	0.371
Scrotal oedema	0.0	0.597	Fixed model	4.25 (2.40, 7.54)	0.000	1.000
Wound infection	0.0	0.755	Fixed model	0.41 (0.07, 2.43)	0.328	1.000
Natural conception	0.0	0.549	Fixed model	0.80 (0.58, 1.09)	0.155	0.602

Improvement of semen parameters

Regarding increased motility and sperm concentration, the results do not support microsurgical varicocelectomy with testicular delivery (sperm motility: SMD = 0.33, 95% CI = -0.39 to 1.04, p = 0.367; sperm concentration: SMD = - 0, 35.95% CI = - 1.08 to 0.37, p = 0.558) (Table 3). At follow-up of 3, 6 months and one year, advanced motile semen achieved similar results (p> 0.05) (Table 4). The SMD collected in connection with an increase in the total sperm count suggested that microsurgical resection with TD could help in the overall sperm count in the short term (3 months later: SMD = 0.23, 95% CI = 0.02-0.44, p = 0.032; after 6 months: SMD = 0.21, 95% CI = 0.04-0.39, p = 0.015), no long-term difference was observed (one consecutive year: SMD = -0, 07, 95% CI = - 0.47 to 0.32, p = 0.710) (Table 4).

Table 04: Improvement of semen parameters

Improvement of progressively motile spermatozoa (%)						
Outcomes	**I2 (%)**	**Heterogeneity**	**Effect model**	**SMD (95% CI)**	**p-value**	**Begg's test p**
3 months follow-up	97.9%	0.000	Random model	−0.55 (−2.15, 1.06)	0.503	0.806
6-month follow-up	99.5%	0.000	Random model	1.22 (−2.48, 4.93)	0.518	0.806
1-year follow-up	-	-	-	−0.18 (−0.57, 0.21)	0.374	0.806
Improvement of total sperm count (106 per ejaculation)						
3-month follow-up	49.8%	0.136	Fixed model	0.23 (0.02, 0.44)	0.032	0.308
6-month follow-up	0.0%	0.685	Fixed model	0.21 (0.04, 0.39)	0.015	0.308
1-year follow-up	-	-	Fixed model	−0.07 (−0.47, 0.32)	0.710	0.308

Natural conception and improvements of serum testosterone

Single study (Hou et al., 2015) conveyed data on natural conception 1 year after removal of enlarged scrotum vein and single study (Nie et al., 2017) conveyed data on advancement of serum testosterone. When it came to natural conception, the pooled RR demonstrated that no variance was found amid the two methods 1 year after removal of enlarged scrotum vein (RR = 0.80, 95% CI = 0.58–1.09, p = 0.155) (Table 3). We also observed resembling results in terms of the serum testosterone improvement.

Subgroup analysis in Level II-III varicocele

Two studies (Allameh et al., 2018; Li et al., 2017) reported level II and III of enlarged vein of the scrotum in patients that participated in the study. Overall sperm count (SMD = 0.23, 95% CI = 0.07-0.39, p = 0.258) in microsurgical resection with testicular delivery compared to microsurgical resection without testicular delivery, sperm count with testicular delivery increases significantly (SMD = 0.23, 95% CI = 0.07-0.39, p = 0.258) but sperm motility, sperm concentration and gradual increase have no change in between the two microsurgical methods (p> 0.05)

Assessment of sensitivity analyses and publication bias

An example of sensitivity analysis was provided for assessing the reliability of this meta-analysis, and for evaluating the impact of each article on the combined outcome by downloading each study that participated in turn. We performed Begg and Egger tests to measure the publication partiality of this meta-analysis. Our outcomes showed that no bias was found, and that the combined results were stable ($p > 0.05$, Table 2- 4).

DISCUSSION

Microsurgical sub-inguinal ligation of scrotum veins (MSV) or microsurgical inguinal removal of enlarged scrotum vein (MIV) can increase the surgical area to protect the testicular arteries and lymph vessels, in addition to banding of the gubernacular veins (27). Also, MSV or MIV may be more beneficial in sperm count and movement. Compared to other surgical methods, microsurgery can increase spontaneous pregnancy rates and reduce recurrence and testicular edema (28).

Although the therapeutic effect of MSV and MIV is better than conventional open or laparoscopic surgeries, recurrence still exists and the main factors of relapse after surgery are discussed. Murray et al. (1986) found that 7% of patients with recurrent enlargement of veins experienced gubernacular vein dilation may be the major cause of recurrence (29). While on the other side, Goldstein, Gilbert, Dicker, Dvush, and Genko (1992) found that MSV with TD could significantly reduce the rates of recurrence and testicular edema (30).

In particular, it is not clear whether MSV requires to move the gubernacular vein in the testicle and its ligation. Hoh et al. (2015) evaluated the effect of testicular delivery on complications and recurrence of MSV in adults. In Hoh et al. study, 100 fertile adult men diagnosed with varicocele, are randomly assigned by MSV with or without testicular delivery (31). Compared to MSV without testicular delivery, MSV with testicular delivery does not lower the recurrence rate and has a higher risk of complications.

However, Spinelli et al. (2016) found that left testicular volume gets increased significantly by MIV with testicular delivery and ligation of all the security veins and gubernacular veins compared to MIV without testicular delivery (32). On the other side, Almi et al. (2018) performed an RCT, in which he compared two MIV methods in patients with level III varicocele. None of the methods cause relapse or scrotal oedema (33). The main difference was that sperm motility increased significantly in men with MIV testicular delivery.

According to the above explanation, it is still controversial whether a patient should undergo testicular delivery during varicocelectomy. In this systematic review and meta-analysis, we included 367 TD patients, 5 RCTs, and 753 varicocele patients, including 386 cases of microsurgical varicocelectomy without testicular delivery, relative to potential papers comparing microsurgical shades with and without testicular delivery. Study concluded that findings conclude that MSV with testicular delivery may have a higher rate of seborrheic adenitis in the testis and scrotal edema. Our findings show that microsurgical resection with testicular delivery does not cause severe incidence of varicocele and wound infections. Semen parameters are important parameters in evaluating the advantages and disadvantages of testicular delivery. Analysis of sperm parameters after microscopic vascular resection showed no differences in sperm motility, sperm concentration, and gradual increase in sperm motility between the two groups.

In the short term, the increase in testicular delivery group sperm count alone was better than that of the microsurgical resection without the testicular delivery group, but there was no significant difference in the long term. In addition, similar results were obtained for sperm parameters for level II and III varicose veins. The collective findings also illustrate that a longer surgery time is required for microsurgical resection with testicular delivery compared to microsurgical resection without testicular delivery.

This meta-analysis has a number of benefits that cannot be ignored. First, a comprehensive literature searches and auxiliary screening was conducted to search for as many quality articles as possible to make the research more reliable and stable. Second, compared to previous surveys, we included a larger sample size in our study. Thirdly, we made many stratified investigations based on varicose vein classification and follow-up sessions to achieve further outcomes. In addition, the results and conclusions gathered through sensitivity analysis and presentation of bias, results were found to be reliable and convincing. This research provides more credible and compelling conclusions, but there are still some limitations. Most importantly, despite strict inclusion and exclusion criteria, heterogeneity is still observed in some outcomes. Therefore, a significant decrease in heterogeneity after varicocele classification and stratification of the follow-up time. In addition, the statistical power was limited due to the relatively small number of RCTs studies and research subjects in several surgeries (e.g. comprehensive sperm count) during the one-year follow-up period. Therefore, further research is required to concentrate on this topic and make the results more considerable.

CONCLUSION

In conclusion, as a result of this systematic review and meta-analysis, compared with MSV without TD, delivery of the testicles during microsurgery to further ligate the gubernacular veins leads to testicular epidermitis and edema, and longer surgery. In addition, TD may not improve parameters of sperm, serum testosterone and incidence of varicose veins, wound inflammation and spontaneous pregnancy compared to non-delivered testicles. However, a higher level of research is needed to determine if TD is an important surgery in microsurgical vascular resection.

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