

Comparison of Success Rate and Complications of Open Inguinal and Subinguinal Varicocelectomy: A Randomized Controlled Trial

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Abstract

Background: Varicocele is the most common surgically correctable cause of infertility in men. The aim of this study was comparing the success rate and complications of open inguinal and subinguinal varicocelectomy.

Methods: This randomized clinical trial was conducted from March 2017 to 2018. Sixty six patients that met inclusion criteria for varicocelectomy (persistent pain or impaired spermogram) were sequentially randomly allocated to inguinal and subinguinal varicocelectomy. Sperm analysis was performed in all patients before surgery. One week, one and three months after the operation patients were visited and evaluated for pain intensity (using visual analog scale) and complications(recurrence, hematoma, scrotal swelling, infection, hydrocele formation and numbness). Follow- up spermogram was done three months after varicocelectomy to evaluate the success of operation.

Results: Mean time of operation was 17.33 ± 2.18 and 22.48 ± 4.45 minutes in the subinguinal and inguinal varicocelectomy method, respectively ($p=0.001$, $CI_{95\%}=3.41-6.89$). Semen analysis three months after surgery showed that there was no significant differences between semen volume ($p=0.85$), sperm count ($p=0.09$), sperm density ($p=0.13$), normal morphology ($p=0.07$) and motility ($p=0.47$) in both groups. There was no significant difference in pain density one week ($p=0.51$), one ($p=0.29$) and three months ($p=0.67$) after surgery between two groups. There wasn't any significant difference between two groups regarding recurrence of varicocele ($p=0.67$).

Conclusions: In this study subinguinal varicocelectomy was superior to inguinal method due to less time of operation. However, there was no significant difference in postoperative complications and improvement of spermogram. Further studies with longer period of follow-up are recommended to compare fertility rate in inguinal and subinguinal varicocelectomy.

Trial registration: IRCT, IRCT201710131323N12, Registered 20 October 2017, Retrospectively registered, <https://www.irct.ir/trial/581>

Introduction

Infertility is one of the most important health issues of society, which is observed in 15% of young couples of reproductive age and imposes many psychosocial, emotional and economic effects on community health. [1, 2]

Varicocele is the most common surgically correctable cause of infertility in men which may be familiar and, in some studies, had some relation to prostate cancer. [3, 4] Early diagnosis and treatment of varicocele, as the major cause of male infertility, can play an important role in improving infertility and reducing harmful effects on testes and also related costs. [5, 6]

There are several methods for the surgery of varicocele, including microscopic surgery (inguinal and subinguinal), laparoscopic, open surgery and interventional radiology. [7- 10]

Inguinal and subinguinal methods are recently developed as surgical techniques that in both methods, during operation all veins except the vassal vein are ligated, while lymphatic and if possible testicular arteries are preserved. Consequently, it reduces recurrence and complications. [1, 11] In this study, we compare success rate and complications of open inguinal and subinguinal varicocelelectomy.

Methods

It was a simple blind randomized clinical trial that was conducted from March 2017 to 2018. This study was approved by ethics committee of Yasuj University of Medical Sciences. After obtaining informed consent, 66 eligible patients that met inclusion criteria (persistent pain and/or impaired spermogram) enrolled study and were randomly allocated (sequential) in one of two groups of inguinal and subinguinal varicocelelectomy (Fig. 1).

In both groups, after taking history and physical examination, diagnosis of varicocele were confirmed by examination and ultrasonography. Then sperm analysis was performed and sperm parameters were recorded in all patients. All operations were performed by a single surgeon with two methods of inguinal and subinguinal varicocelelectomy.

In both methods after operation, patients transferred to recovery and were discharged in the absence of any complication. One week after operation patients were visited again and evaluated for pain intensity using visual analog scale, hematoma formation, scrotal swelling and infections of operation site by surgeon. One and three month later, patients were revisited and evaluated for pain intensity, varicocele recurrence, hydrocele formation and presence of numbness in the site of operation by examination and/or ultrasonography, again. After three months, Follow up spermogram was done for all patients to assess the success of operation.

A sample size of 80 patients was calculated using comparing two mean formulas counting 10% attrition rate. It was estimated to yield 80% power (type II or beta error of 0.20%) and type I error of 0.05 ($\mu_1 = 48 =$ Mean of sperm motility in open inguinal varicocelelectomy, $\mu_2 = 52 =$ Mean of sperm motility in microscopic subinguinal varicocelelectomy, $S_1 = 4 =$ S.D. of sperm motility in inguinal varicocelelectomy, $S_2 = 6 =$ S.D. of sperm motility in microscopic subinguinal varicocelelectomy). [6]

Ethical considerations

The research followed the tenets of the Declaration of Helsinki. Informed consent was obtained .The research was approved by the ethical committee of Yasuj University of Medical Sciences (Ethic code: ir.yums.REC.1395.220) and was registered in the Iranian Registry of Clinical Trial (IRCT) with code number of IRCT201710131323N12.

Statistical analysis

Data were analyzed by SPSS 21 software using descriptive (frequency, mean and standard deviation) and analytical (independent sample T test, chi-square) statistics. P value < 0.05 was considered as the significant level.

Results

Sixty six patients completed the study. Demographic characteristics of participants are summarized in Table 1.

Table 1
Demographic characteristics of participants based on surgical method

variables	Method of varicocelectomy		P-value	CI _{95%}	
	Inguinal	Subinguinal		Lower limit	Upper limit
Age (year):	13(39.4%)	20(60.6%)	0.08 ^a	-	-
- 21–29	20(60.6%)	13(39.4%)			
- 30–39					
Varicocele side:	0(0%)	1(3%)	1 ^c	-	-
- Right	33(100%)	32(97%)			
- Left					
Varicocele grade:	8(24.24%)	2(6.1%)	0.07 ^a	-	-
- 1	17(51.52%)	17(51.5%)			
- 2	8(24.24%)	14(42.4%)			
- 3					
^bSemen analysis:	4.4 ± 1.8	3.74 ± 1.66	0.12	-0.19	1.51
- Volume(ml)	68.6×10 ⁶ ±49.21×10 ⁶	72.09×10 ⁶ ±43.87×10 ⁶	0.76	-26.42	19.43
- Count	15.36 ± 12.42	19.73 ± 12.00	0.15	-10.37	1.63
- Density	57.78 ± 26.98	48 ± 23.54	0.12	-2.66	22.24
- Normal morphology	45.66 ± 24.99	45.63 ± 18.89	0.99	-10.86	10.92
- Normal motility					
a Chi-Square test was used for analysis					
b Independent samples T test was used for analysis					
c Fisher's Exact test was used for analysis					

Mean time of operation in the subinguinal and inguinal methods was 17.33 ± 2.18 and 22.48 ± 4.45 minutes respectively (P = 0.001, CI_{95%}=3.41–6.89).

Three months after surgery, there wasn't any significant differences between two groups in result of semen analysis (Table2).

Table 2
Semen analysis three months after varicocelectomy based on method of surgery

Semen analysis	Method of varicocelectomy		P-value ^a	CI _{95%}	
	Inguinal	Subinguinal		Lower limit	Upper limit
- Volume(ml)	3.83 ± 1.87	3.76 ± 1.14	0.85	-0.69	0.83
- Count	69.73×10 ⁶ ±47.43×10 ⁶	92.56×10 ⁶ ±57.65×10 ⁶	0.09	-48.23	3.69
- Density	19.31 ± 13.84	24.07 ± 11.85	0.13	-11.09	1.58
- Normal morphology	65.15 ± 21.79	55.45 ± 20.87	0.07	-0.79	20.19
- Normal motility	54.36 ± 21.08	57.48 ± 13.12	0.47	-11.78	5.54

a Independent samples T test was used for analysis

In inguinal varicocelectomy, there was significant difference before and after surgery in sperm density (P = 0.008), normal morphology (P = 0.0001) and normal motility (P = 0.0001) in semen analysis but there wasn't any significant difference in semen volume (P = 0.14) and sperm count (P = 0.88).

In subinguinal varicocelectomy, there was significant difference before and after surgery in sperm count (P = 0.017), sperm density (P = 0.0001), normal morphology (P = 0.0001) and normal motility (P = 0.0001) in semen analysis but there wasn't any significant difference in semen volume (P = 0.96).

There was no significant difference in pain intensity one week (p = 0.51), one (p = 0.29) and three months (p = 0.67) after surgery between two groups. There wasn't any report of hematoma formation, scrotal swelling and infections one week after surgery in both groups. There wasn't any report of pain, hydrocele formation and paresthesia in the site of operation, one and three months after surgery in both groups. There wasn't any significant difference in varicocele recurrence three months after surgery in inguinal and subinguinal varicocelectomy, respectively (12.1% vs. 6.1%, P = 0.67).

Discussion

Varicocele is the most common correctable cause of male infertility that may cause severe oligospermia and even azoospermia in some patients. [12-14]. Recently two systematic reviews concluded that there isn't sufficient evidence regarding treatment of varicocele and its relation to fertility to warrant their repair. [14, 15] However many studies reported fertility rate of 30-50% after different type of operation. [2, 6, 16]

At present inguinal, subinguinal, microsurgical and laparoscopic methods are performed with different success rate and complications. [7, 9, 17] This study was performed for comparison of success rate and complication of open inguinal and subinguinal varicocelectomy.

According to our results, there was no significant difference between two groups regarding patients' age, site and grade of varicocele and semen analysis parameters before operation. Mean time of operation was significantly lower in subinguinal varicocelectomy.

In study by Watanabe and his colleagues, mean age of patients was 33.1 ± 5.9 year and grade 2 was the most common type of varicocele. Mean time of operation was 28.4 ± 3.86 minutes that was less than other studies. [1] Results of our study are similar to this study regarding mean age of patients and varicocele grades but the mean time of operation was lower in our study. In AL-kandari study the mean time of operation in subinguinal method was longer than laparoscopic and open group. [6] Also in Shiraishi study and his colleagues, the time of operation in subinguinal method was more than laparoscopic and open methods and postoperative pain in subinguinal method was less than other methods. [7] These results are in contrast to our results and mean time of operation in subinguinal group was less than inguinal method in our study. This difference may be due to type of anesthesia that in some patients was regional or inappropriate answers of patients to questionnaire. Regarding recurrence rate and complications in Shiraishi study, subinguinal method showed lower rate than other methods which is in concordance with our results. [7]

Three months after operation sperm analysis revealed that there was no significant difference between two groups regarding semen volume and sperm parameters such as count, density, morphology and density. On the other hand, intergroup comparison showed that in both methods sperm density, morphology and motility improved after operation and sperm count improved more in subinguinal method ($p = 0.017$). These results are similar to Watanabe and Shiraishi studies, [1, 7] but in contrast to these studies, in the present study both sperm density and motility improved with higher improvement in subinguinal varicocelectomy.

Regarding postoperative complications there was no case of hematoma, scrotal swelling, infection, pain and inguinal paresthesia one week to 3 month after operation in both groups. In this study, there wasn't any significant difference in varicocele recurrence, three month postoperatively between two groups. These results are similar to Watanabe et al, except that in their study there was no recurrence in subinguinal method but we have two cases of recurrence in this method that may be due to non-microscopic method. [1]

Regarding postoperative pain, other studies reported different results; but in all of them, pain intensity was higher than our study, [1, 6-7] which may be due to small incision in our study.

With regard to importance of infertility in our society we suggest further studies with longer duration of follow up to compare fertility rate in inguinal and subinguinal varicocelectomy.

Conclusions

In this study subinguinal varicocelectomy was superior to inguinal method due to less time of operation. However, there was no significant difference in postoperative complications and improvement of spermogram, the necessity of further studies with longer duration of follow up to compare fertility rate in inguinal and subinguinal varicocelectomy is felt.

Declarations

- **Ethics approval and consent to participate:**

The research was approved by the ethical committee of Yasuj University of Medical Sciences (Ethic code: IR.YUMS.REC.1395.220). Informed consent was obtained from all participants.

- **Consent for publication:**

Not applicable

- **Availability of data and materials:**

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

- **Competing interests:**

The authors declared that they have no competing interest.

- **Funding:**

Deputy of research of Yasuj University of Medical Sciences.

- **Authors' contributions:**

SM; the concept, design, data analysis, and manuscript preparation, manuscript review and final revision and submission. LM; the concept, design, data analysis, and manuscript preparation, manuscript review and final revision and submission. FSh; writing proposal and data collection. AM; writing proposal and data collection.

All authors read and signed the final paper.

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Figures

CONSORT 2010 Flow Diagram

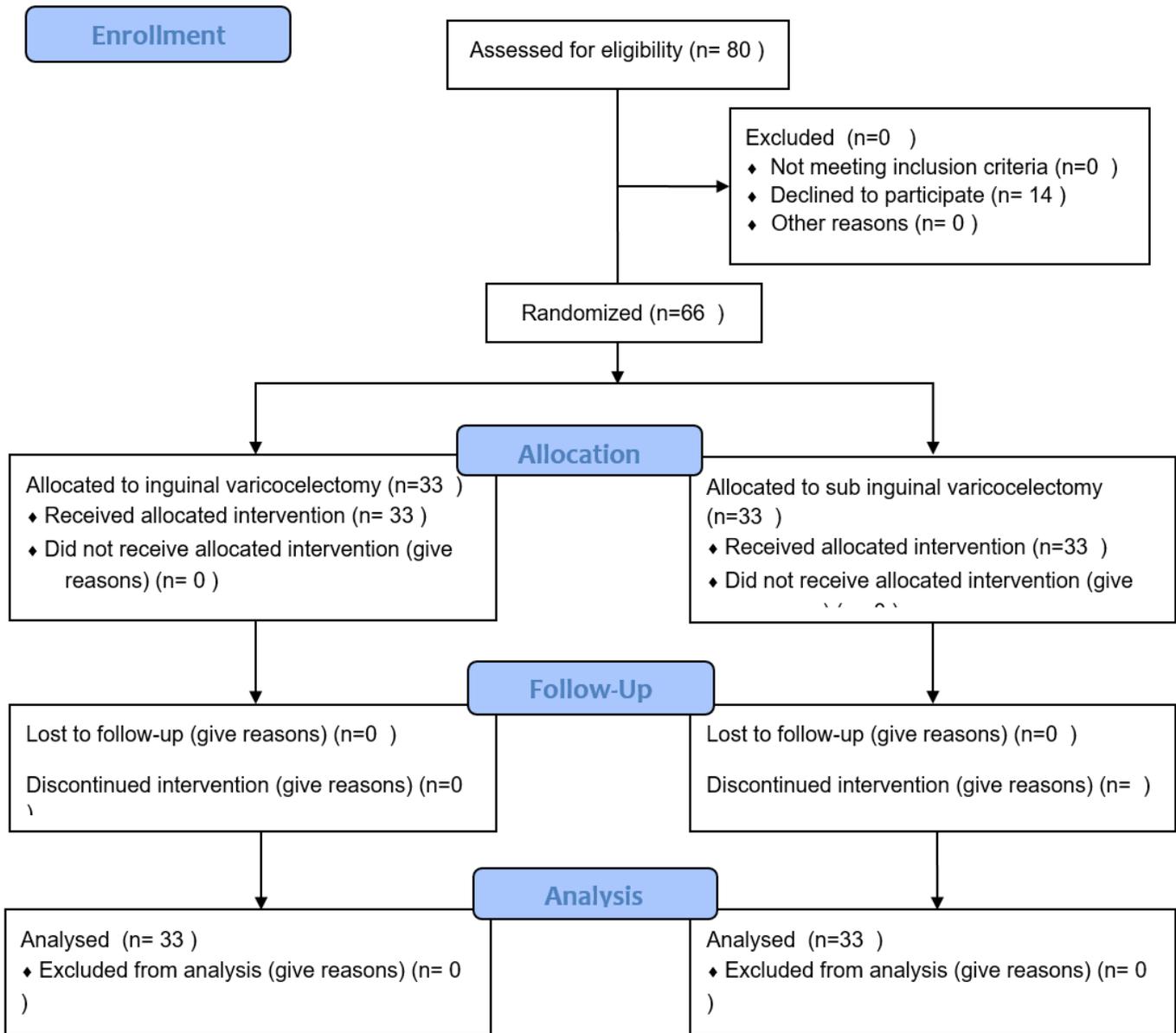


Figure 1

CONSORT 2010 Flow Diagram