



A comparative study of fascial sheath interposition versus no fascial sheath interposition in No Scalpel Vasectomy

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How to cite this article: Satish Kumar Bansal, Sham Singla, Gopal singal, Sanjay Gupta. A comparative study of fascial sheath interposition versus no fascial sheath interposition in No Scalpel Vasectomy. IAIM, 2015; 2(3): 73-78.

Available online at www.iaimjournal.com

Received on: 20-02-2015

Accepted on: 27-02-2015

Abstract

Background: Since the introduction of male sterilization by surgery on vas deferens, several techniques have emerged to improve the results in terms of time, invasiveness, post operative infection, complications and success rate.

Introduction: Vasectomy was introduced by Sharp in 1897. No scalpel vasectomy was introduced in China by Dr. Li Shun-Qiang in 1974. Intact fascial sheath helps in restoration of vas lumen and fascial sheath interposition prevents recanalization of vas by prevention of meeting of epithelialization from cut end of vas.

Material and methods: The study was performed at PGIMS, Rohtak by performing surgery and follow-up up to one year of 326 subjects of no scalpel vasectomy. Clients were allocated in two groups. Group - A (155) with fascial sheath interposition and Group - B (171) without fascial sheath interposition. Surgeries were performed as a routine surgical procedure after full preparation of client including consent.

Results: Majority of clients (56.1%) in Group - A were in age group 31-40 years followed by 22-30 years (28.4%), 41-50 years (14.8%) and 0.7% in age group more than 50 years. In Group - B, majority were also in age group 21-30 years (63.7%), followed by 31-40 years (29.8%), 41-50 years (5.9%) and 0.6% were of above 50 years. In Group - A, fascial sheath interposition was not possible in 17.2% clients due to non separation of sheath from vas. Sperm granuloma formation was observed in 8.6% in Group - A and 5.6% in Group - B. In comparison of 100% success rate in Group - A failure rate of 1.8% was observed in Group - B.



Conclusion: The present study supports the existing literature that fascial sheath interposition adds a little more to the operating time of vasectomy, increases chances of wound infection and granuloma but has a less failure rate of vasectomy.

Key words

No Scalpel Vasectomy, NSV, Fascial sheath interposition.

Introduction

Male sterilization i.e. vasectomy was introduced by Sharp in 1897 [1]. Over the years it has established as a simple, safe, permanent and relatively inexpensive minor surgical procedure [2]. The term vasectomy in its true sense is a misnomer. It literally means complete excision of vas. However years of usage of this term has established it as a procedure of interrupting continuity of vas deferens. It essentially involves two steps i.e. exposure of vas followed by occlusion of vas. Exposure of vas may be achieved by conventional technique of single/double scrotal skin incision or by no-scalpel vasectomy. The latter requires special instruments to hold the vas percutaneously and deliver it out of scrotum through a small hole in the scrotal skin. It was developed by Dr. Li Shun-Qiang in China in 1974 [3]. Controlled trials have shown that No-scalpel vasectomy (NSV) is the safer and faster method of exposing the vas resulting in fewer complications and increased patient acceptability than the conventional incisional technique [4, 5, 6, 7]. In spite of so many modifications introduced in the technique of vasectomy failures still haunt the surgeons. Failure of vasectomy may be early or late [8, 9, 10, 11]. Early failure of the procedure is considered to have occurred when significant number of spermatozoa or any motile spermatozoa persists continuously in semen analysis even after four months after vasectomy. Ideally two consecutive semen analysis at least four weeks apart, 2-4 months after vasectomy have been recommended to determine azoospermia or to detect early failure [12, 13,

14, 15, 16, 17, 18] The most common reason of a failed vasectomy is spontaneous recanalization of the vas deferens [19, 20]. Intact fascial sheath helps in restoration of the vas lumen by acting as a conduit and directing the path for epithelialization [21]. If the sperms do not reach distal end spermatic granuloma develops [22, 23].

Material and methods

It was a prospective randomized controlled study carried out at Pt. B.D. Sharma Postgraduate Institute of Medical Sciences, Rohtak and various district hospitals of Haryana from March 2003 to March 2005. It included 326 men who underwent no scalpel vasectomy. They were randomly allocated to two groups Group - A and Group - B. Group - A (study group) included 155 men in whom no scalpel vasectomy was done with fascial sheath interposition (FSI). Group - B (control group) included 171 men in whom no scalpel vasectomy was done without fascial sheath interposition. Detailed history was taken regarding age, address, educational status of the couple, number of children, age of the youngest child and any chronic illness. A general and local examination of the scrotum was carried out. Persons having dermatitis, infection of scrotum, hernia, hydrocele or varicocele were excluded from the study. Routine investigations like hemoglobin, bleeding time, clotting time and complete urine examination were carried out. Surgeries were performed as a routine surgical procedure after full preparation of the client including consent. In Group - A (study group),

the tie of testicular end was cut short and both ends were allowed to retract back into spermatic fascial sheath by pulling the testis downwards within the scrotum. Thread on the abdominal end of the vas was then slowly pulled outside. It often came out covered with fascial sheath. The visible fascial sheath was tied over it with a silk 2-0 suture. In Group - B (control group), no fascial sheath interposition was done following conventional vasoligation and both cut ends were allowed to lie inside the spermatic fascial sheath. Each patient was advised to come for follow up on third and seventh postoperative day for wound inspection or any other complaint and after two months (or 20 ejaculations) following vasectomy for semen analysis. One more follow up was done after one year for repeat semen analysis, persistence of pain or any other complication. Data thus obtained were analyzed as per standard statistical methods.

Results

All the patients (326 men) who underwent vasectomy at Pt. B.D. Sharma Post Graduate Institute of Medical Sciences, Rohtak and various district hospitals of Haryana were allocated randomly to two Groups A and B. In Group - A (study group), there were 155 men in whom ligation and excision of vas followed by fascial sheath interposition on abdominal end was performed. In Group - B (control group), there were 171 men in whom only ligation and excision was done for occlusion of vas. Age pattern of vasectomy acceptors was as per **Table – 1**. Educational status of acceptors was as per **Table – 2**. Locality wise distribution of acceptors was as per **Table – 3**.

Majority of the clients in both groups i.e. 60% and 57.3% were self motivated by advertisements through pamphlets, posters, banners, newspapers and other modes of

media. Four persons (1.2%) out of the whole study developed bradycardia, hypotension and sweating during operation. It was possibly because of vasovagal attack following holding of unanesthetised vas percutaneously. Hematoma was defined as large if it was double the size of normal scrotum and if less than double, it was taken as small hematoma. Two cases of large hematoma were observed during this study, one in each group and these hematomas were large enough and required drainage. The wound was taken as mildly infected if it was red and edematous, moderately infected if it had serous discharge and severely infected if it had frank purulent discharge or got opened. Six cases in Group - A and only 1 case in Group - B had mild infection while the severe infection cases numbered only 1 each in both the groups. All clients were sent home after 1 hour of observation. Majority of the cases in both groups i.e. 66.3% and 65.7% respectively resumed their daily work by the next day. Majority of the clients 91.5% returned to their normal work within 3 days. Almost all 97.6% cases resumed their normal work within 7 days. Sperm granuloma was observed in 9 Group - A and 6 Group - B cases and the difference in incidence of sperm granuloma formation in the two groups was statistically insignificant ($p>0.05$). Follow up rate was as per **Table – 4**.

Discussion

Jackson, et al. in their series reported that 62% of the acceptors belonged to 30-39 years of age group [2]. Similarly, 57.44% of acceptors were from 31 to 40 years of age as reported by Lehtonen and Juusela. In present study also about two thirds of the acceptors (60.1%) belonged to 31-40 years age group. Barne, et al. reported vasovagal in 2.4% cases [8] in a series of 1000 cases which is almost double to that of present study wherein vasovagal reaction was observed in 4 cases (1.2%) because of pain

Table - 1: Age pattern of vasectomy acceptors.

Age in years	Group - A No. (%)	Group - B No. (%)	Whole study No. (%)
21-30	44 (28.4)	51 (29.8)	95 (29.2)
31-40	87 (56.1)	109 (63.7)	196 (60.1)
41-50	23 (14.8)	10 (5.9)	33 (10.1)
>50	1 (0.7)	1 (0.6)	2 (0.6)
Total	155	171	326

Table - 2: Educational status of acceptors.

Education	Group - A No. (%)	Group - B No. (%)	Whole study No. (%)
Illiterate	8 (5.2)	17 (9.9)	25 (7.7)
Primary	22 (14.2)	34 (19.8)	56 (17.2)
Middle	24 (15.5)	22 (12.9)	46 (14.1)
Matric	74 (47.7)	72 (42.1)	146 (44.8)
Graduate	27 (17.4)	26 (15.2)	53 (16.2)
Total	155	171	326

Table - 3: Rural and urban distribution of acceptors.

Locality	Group - A No. (%)	Group - B No. (%)	Whole study No. (%)
Rural	64 (41.3)	72 (42.1)	136 (41.7)
Urban	91 (58.7)	99 (57.9)	190 (58.3)
Total	155	171	326

Table - 4: Follow up rates.

Follow up after	Group - A No. (%)	Group - B No. (%)	Whole study No. (%)
3 days	150 (96.8)	164 (95.9)	314 (96.3)
1 week	144 (92.4)	158 (92.7)	302 (92.6)
2 months	123 (79.4)	130 (76.0)	253 (77.6)
3 months	111 (71.6)	116 (67.8)	227 (69.6)
4 months	107 (69.0)	112 (65.5)	219 (67.2)
1 year	104 (67.1)	108 (63.2)	212 (65.0)

during the start of procedure. It was possibly because of vasovagal attack following holding of unanesthetised vas percutaneously. Although reported range of hematoma formation in NSV

without FSI varies from 0.15 to 7.1 but it is below 2% in most of the series [7, 9, 10, 11]. Comparable incidence of hematoma formation (0.9%) was observed without FSI in Group - B of

our series. Reported incidence of hematoma formation with FSI ranges from 0.07-1.4% which is also comparable with less than 1% in our series [3, 4, 6, 9, 11]. Li, et al. reported 0.91% infection rate but criteria of infection was not mentioned [3]. Nirapathpongorn reported an infection rate of 0.2% with standard NSV [4]. Sokal, et al. reported a similar infection rate of 0.48% in both with and without fascial sheath interposition [11]. Persistence of redness and edema on third day was considered as infection in our study. A wound was taken as mildly infected if it was red and edematous, moderately infected if it had serous discharge and severely infected if it had frank purulent discharge or the wound had got opened. In the present study, 6 cases (5.8%) of mild, 5 cases (4.8%) of moderate and 1 case (0.9%) of severe infection was observed in Group - A whereas in Group - B one case (0.9%) of mild, 2 cases (1.9%) of moderate and 1 case (0.9%) of severe infection were observed. Philip, et al. reported that 80% of cases resumed their normal work within three days and 96% cases within seven days [19]. Randall, et al. reported a good turn up of 88% cases for first follow-up after one week [24]. It gradually decreased to only 53.2% cases at the end of series [23]. Philip, et al. reported a better follow up rate of 95.5% up to end of series. Belker, et al. reported follow up rate of only 54.4% [15]. In the present study of 326 cases 12 cases (3.7%) never returned back even for a single visit. A total of 314 cases (96.3%) came for follow up on third day and 302 cases (92.6%) on seventh day. Follow up rates after 1 week was comparable to that reported by Sokal, et al. [11] and Philip, et al. [15]. Sokal, et al. reported a failure rate of 12.7% when only ligation with excision was carried out and 5.9% when fascial sheath interposition was used in addition. Schmidt reported 3.3% failure with ligation and excision which were reduced to zero by using fascial sheath interposition. The failure rate observed in control group of present study

was 1.8%. No failure was observed in study group using fascial sheath interposition following ligation and excision as a technique of vas occlusion.

Conclusion

The present study supports the existing literature that fascial sheath interposition adds a little more to the operating time of vasectomy, increases chances of wound infection and granuloma but has a less failure rate of vasectomy.

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Source of support: Nil

Conflict of interest: None declared.