



A prospective randomized comparison of sexual function and semen analysis following laparoscopic totally extraperitoneal (TEP) and transabdominal pre-peritoneal (TAPP) inguinal hernia repair

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Abstract

Background With standardization of laparoscopic technique of groin hernia repair, the focus of surgical outcome has shifted to lesser studied parameters like sexual function and fertility.

Methods This prospective randomized study was conducted in a single surgical unit at a tertiary care hospital. A sample size of 144 was calculated with 72 in each group (Group 1 TEP and Group 2 TAPP). Primary outcomes measured included comparison of sexual function using BMFSI, qualitative semen analysis and ASA levels between patients undergoing TEP or TAPP repair. Semen analysis and ASA was measured pre-operatively and 3 months post-operatively.

Results A total of 145 patients were randomized into two groups, TAPP (73) and TEP (72) patients. Both the groups were comparable in terms of demographic profile and hernia characteristics with majority of the patients in both the groups having unilateral inguinal hernia (89.0% in TAPP group and 79.2% in TEP group). Both the groups showed statistically significant improvement in overall sexual function score (BMFSI) at 3 months; however, there was no inter group difference. Both the groups were also comparable in terms of ASA and qualitative semen analysis.

Conclusion Both TEP and TAPP repair are comparable in terms of sexual function and effect on semen analysis. Laparoscopic repair improves the overall sexual functions in patients with groin hernia.

Keywords Groin hernia · Sexual functions · TAPP · TEP · Semen analysis

Laparoscopic groin hernia repair has become standard of care for patients with groin hernia. Recent literature has shown that quality of life (QoL)-related outcomes and patient-related outcomes like return of activity,

psychological wellness are important following any surgical intervention [1]. There are few contradicting reports on the effect of groin hernia repair on the testicular function and sexual function. In one of our previous studies who have shown that the testicular function as well as sexual function are similar following open as well as TEP or TAPP repair [2]. The sexual function following TEP or TAPP repair have not been compared in a randomized study. Recent reports indicate that improvement of QoL-related issues is the main reason why patients undergo elective inguinal hernia repair. While chronic pain has been the subject of several studies, little is known about sexual functions in patients with inguinal hernias. Symptoms associated with an inguinal hernia can affect sexual function and surgical repair may improve quality of (sexual) life [1, 3].

Genital pain and dysejaculation following inguinal hernia repair have been described too [4–7]. There are very few studies regarding quality of sexual functions after inguinal

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hernia repair [4–6]. Endoscopic repair techniques are associated with less post-operative pain and earlier return to normal activities and there are two standard techniques of laparoscopic groin hernia repair, transabdominal preperitoneal (TAPP) and totally extraperitoneal (TEP) [8]. Randomized trials comparing TAPP and TEP techniques have shown comparable short-term outcomes except for a slightly higher incidence of early post-operative pain following TAPP repair [9].

There are very few randomized studies comparing TAPP and TEP techniques in terms of chronic groin pain and Quality of life. Although animal studies have suggested a strong correlation between mesh inguinal hernia repairs and structural damage to elements of the spermatic cord and testicle [10], this has not translated into a clinically significant infertility rate after open or laparoscopic inguinal hernia repair [11]. Moreover testicular perfusion is also impaired pre-operatively on affected (hernia) side which is reflected by elevated sonographic resistive index [3]. Measurement of testicular volume with resistive index, measurement of serum levels of sex hormones and semen analysis are some of the surrogate markers for measurement of testicular function.

Anti-sperm antibodies (ASA) are present in 10% of infertile men [4]. ASA disturb sperm penetration through cervical mucus, binding of sperm and egg, as well as the acrosomal reaction [11]. There is also a connection between ASA and low sperm count and motility. Presently there is no study comparing TEP and TAPP in terms of effect on semen analysis and production of ASA. This study was designed as a prospective randomized comparison to evaluate sexual function and effect on semen analysis following TAPP or TEP repair.

Methods

This prospective randomized study was conducted in a single surgical unit at a tertiary care hospital. Consecutive patients undergoing laparoscopic repair of groin hernia were randomized to either TEP or TAPP repair. An informed consent was taken from all the patients and only patients who gave consent for randomization were included.

The study was conducted as per the CONSORT guidelines after due clearance from the Institutional Ethics Committee and ICMR/GCP guidelines for randomized trials was followed. The study was registered in Clinical Trial Registry of India (registration no CTRI/2018/05/013,621). The details of patients who refused consent and reason for refusal of consent were noted. Refusal for consent for inclusion in the study didn't hamper the treatment of these patients in anyway.

The sample size calculation was based on equivalence trial to see overall effect on testicular function following laparoscopic inguinal hernia repair by TEP and TAPP. With proportion of effect on sexual function following TEP of 9% [12] and 15% in TAPP, with alpha as 5%, power 90% and equivalence margin 20%, a sample size of 144 was calculated with 72 in each group. Considering a dropout rate of 10 percent of patients from the study and loss to follow-up, nearly 75 patients was planned to be included in each group. Randomization was done using computer generated random numbers (www.randomization.com) with sealed envelope to ensure concealed allocation with block randomization. The patients in blocks of eight were randomized into two groups Group I: TransAbdominal Pre-Peritoneal Repair (TAPP), Group II: Totally ExtraPeritoneal Repair (TEP).

All the adult male patients in the age group between 25 and 50 years with primary, uncomplicated, unilateral/bilateral inguinal hernia were included in the study. Patients < 25 and > 50 years, with history of previous surgery in the inguinoscrotal region, recurrent inguinal hernia, complicated hernia, with hydrocele, epididymitis or history of orchiectomy were excluded. Also, patients with significant co-morbidities, unfit for general anesthesia, with uncontrolled coagulopathy and those not giving consent were also excluded from the study.

Primary outcome measures included comparison of sexual function and qualitative semen analysis (including ASA) between patients undergoing TEP or TAPP repair.

Secondary outcome measures included pain and perioperative morbidity.

Pre-operative assessment—The demographic profile, clinical examination findings and laboratory parameters were recorded in a pre-structured proforma.

Semen analysis was done pre-operative and 3 months post-operative. After an abstinence of 2–5 days. The morning samples were collected. The semen was evaluated/ analyzed for:

- Physical characteristics—color, volume, pH, liquefaction time, viscosity
- Microscopic examinations—sperm count, sperm agglutination, total count
- Motility
- Morphological studies.

Anti-sperm antibody (ASA) was measured in the serum sample using commercially available kits pre-operatively and 3 months following surgery using ELISA immunoblot assay.

Pre-operative sexual function was evaluated using the Brief Male Sexual Functioning Inventory (BMSFI). BMSFI developed by O'Leary et al. [13] is open source document and doesn't require permission from original author. The

BMSFI consists of 11 items divided in five functional domains, i.e., sexual drive, erectile function, ejaculatory function, as well as problem assessment of these functional domains, and overall satisfaction. The questions in the BSFI are evaluated on a series of 5-item Likert scales, from 0 or 1 points to 4 or 5 points. Scores are calculated for each of the five functional domains, along with a total BSFI score. It is promoted by the author for use in research work to assess sexual function. It was used pre-operatively and at 3 months.

The patient then underwent standard TEP or TAPP procedure according to the Guidelines of the International Endohernia Society [14]

All patients were followed up was at one week, 1 month, three months and six monthly thereafter. All patients were assessed and examined for presence of wound infection, hematoma, seroma, neuralgia, numbness recurrence. At

3 months a repeat semen analysis and ASA levels were done and the sexual functions were also reassessed.

Statistical analysis—Quantitative data were analyzed by application of student t test / Mann Whitney test. The qualitative data were analyzed by Chi-square test/Fischer test whichever applicable. *p* value < 0.05 was consider significant. Other appropriate statistical analysis was done wherever required.

Results

192 consecutive patients with inguinal hernia were screened during this period. 41 patients were excluded as they either did not meet the inclusion criteria (34 patients) or did not give consent (seven patients) (CONSORT diagram Fig. 1).

Fig. 1 Consort diagram

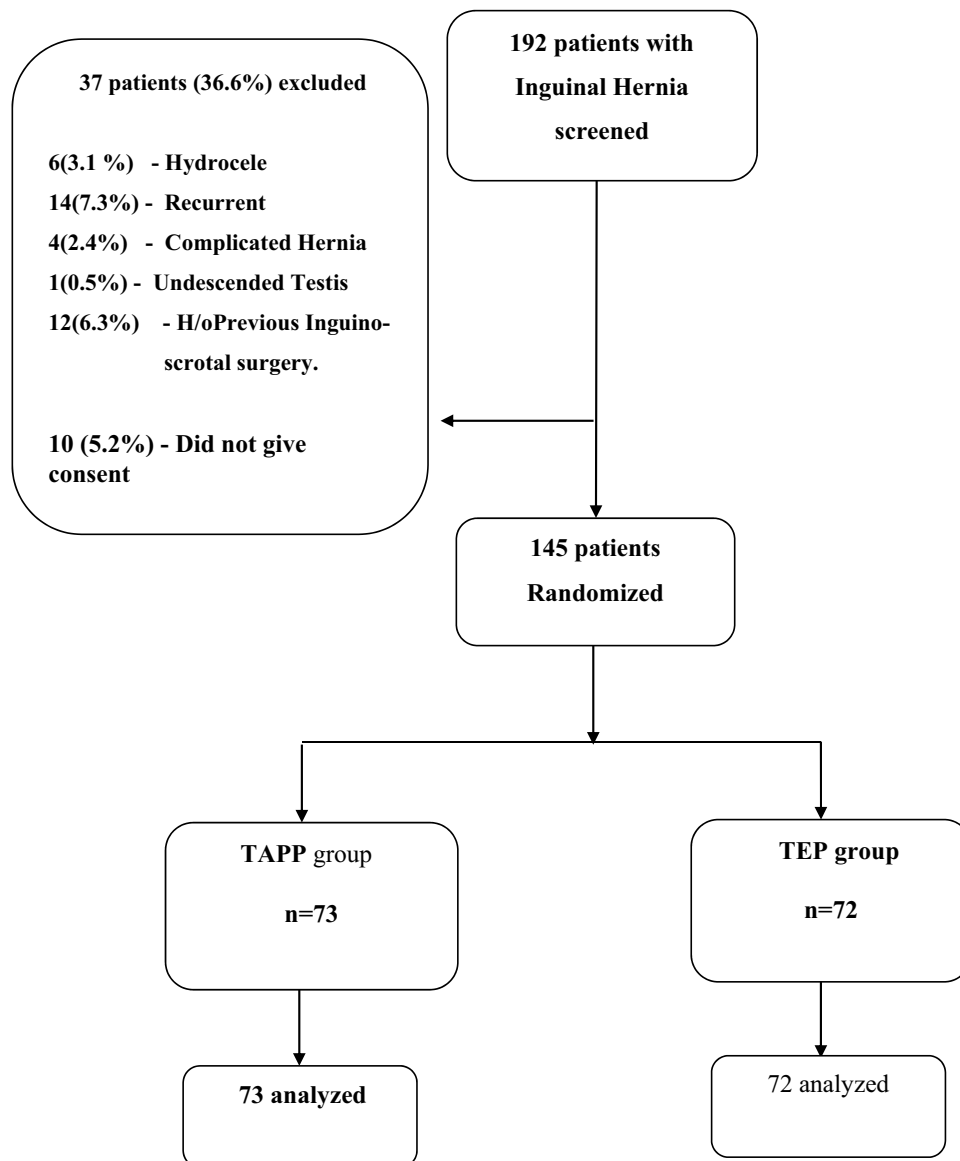


Table 1 Comparison of demographic profile

Demographic profile	TAPP group (n = 73)	TEP group (n = 72)	p value
Age (years)	36.4 ± 7.5	37 ± 8.4	0.72
Mean ± SD (range)	(25–50)	(25–50)	
BMI (kg/m ²)	22.4 ± 1.5	22.2 ± 1.7	0.39
ASA I	69 (94.5%)	68 (94.4%)	
ASA II	04 (5.4%)	04 (5.6%)	0.99

Table 2 Comparison of hernia characteristics

	TAPP group (n = 73)	TEP group (n = 72)	p value
Unilateral (102)	65 (89.0%)	57(79.2%)	0.1
Right	37	38	
Left	28	19	
Bilateral (19)	8 (11.0%)	15 (20.8%)	
Direct	23	27	0.8
Indirect	50	45	0.9

Table 3 Comparison of semen analysis

Parameters	Group	Pre-Op	Post-Op	p value
Semen volume (ml)	TAPP	2.48 ± 0.45	2.47 ± 0.58	0.91
	TEP	2.43 ± 0.51	2.42 ± 0.54	0.92
p value		0.51	0.52	
Semen pH	TAPP	8.07 ± 0.28	8.17 ± 0.24	0.00
	TEP	8.10 ± 0.24	8.20 ± 0.21	0.00
p Value		0.36	0.26	
Sperm concentration (million/cc)	TAPP	48.50 ± 14.10	48.66 ± 12.99	0.98
	TEP	51.50 ± 16.07	51.61 ± 14.61	0.96
p Value		0.28	0.28	
Sperm total count (million)	TAPP	119.26 ± 34.85	120.11 ± 42.27	0.9
	TEP	126.68 ± 52.16	127.72 ± 55.51	0.9
p value		0.36	0.34	
Vitality (%)	TAPP	68.91 ± 8.16	68.95 ± 6.98	0.77
	TEP	68.13 ± 7.07	68.93 ± 7.14	0.79
p Value		0.57	0.65	
WBC count (million/cc)	TAPP	0.31 ± 0.14	0.32 ± 0.12	0.74
	TEP	0.36 ± 0.13	0.37 ± 0.12	0.46
p Value		0.08	0.08	
Progressive motility (%)	TAPP	33.39 ± 9.02	33.79 ± 7.32	0.74
	TEP	35.81 ± 9.36	35.94 ± 6.08	0.84
p value		0.15	0.21	
Non-progressive motility (%)	TAPP	32.45 ± 10.92	34.57 ± 7.20	0.19
	TEP	30.98 ± 7.40	33.85 ± 6.97	0.10
p Value		0.39	0.58	

145 patients were randomized into two groups, TAPP group—73 patients and TEP group—72 patients (Table 1).

Both the groups were comparable in terms of demographic profile and hernia characteristics with majority of the patients in both the groups having unilateral inguinal hernia (89.0% in TAPP group and 79.2% in TEP group) (Table 2).

The average follow-up time was 18 months (Range—3–30 months). All the patients followed up at 3 months, 95% followed up at 6 months and 87% followed up at 18 months (Table 3).

Both the groups showed statistically significant improvement in overall sexual function score (BMFSI) at 3 months [(24.50 ± 2.91 in TAPP group and 24.66 ± 2.82 in TEP Group) to pre-operative score of (27.28 ± 2.95 in TAPP Group and 27.38 ± 2.47 in TEP Group II) at 3 months (*p* value < 0.001)]. There was a statistically significant improvement in the sexual drive score, sexual problem score as well as overall sexual satisfaction score in entire study population. Although there was improvement in the erection and the ejaculation score at 3 months, this was not statistically significant (*p* value > 0.05). On comparison of sexual functions between TAPP and TEP group, there was no statistically significant difference pre-operatively and at 3 months (*p* value > 0.05).

The anti-sperm antibody levels were insignificant both pre-operatively and 3 months post-operatively in the study population and there was no significant difference between the two groups (p value—> 0.05)

Semen Analysis—There was no significant change from the pre-operative level to levels at 3 months in the sperm count, volume, WBC in the study population. Both TEP and TAPP group were also comparable in terms of semen analysis parameters. However, there was statistically significant increase in the semen pH level from the pre-operative value to values at 3 months though this difference was not significant on comparing TAPP group and TEP group.

Discussion

According to the recent IEHS guidelines, laparoscopic hernia repair is one of the standard repairs for groin hernia patients [14]. The technique of TEP and TAPP of laparoscopic inguinal hernia repair is well standardized and randomized control trials have shown that both techniques of laparoscopic groin hernia repair are comparable except for minor differences in early post-operative pain. However the impact of groin hernia surgery on testicular functions, sexual functions and infertility of patients has not been well studied both after open and laparoscopic repair. This is the first study to compare TEP and TAPP in terms of sexual function, semen analysis and ASA

One of the least studied surrogate markers of testicular function is sperm count and anti-sperm antibody levels. Experimental studies have shown that handling of cord structures and resulting fibrosis may lead to breach of blood testes barrier which can result in development of anti-sperm antibody [4]. This antibody in turn causes a decrease in sperm count and possible infertility. However clinical studies in this aspect are lacking. Peeters et al. have reported decrease in sperm motility following laparoscopic mesh repair with light weight mesh in comparison to heavy mesh repair in immediate post-operative period [15]. However, this difference ceased to exist at a follow-up of 1 year. Stula et al. in their study have reported an increase in the anti-sperm antibody (ASA) levels and testicular RI at 3 months follow-up in TAPP repair, but this change was statistically non-significant 6 months post-operatively [16]. This change in the testicular parameters was significantly higher in the open method when compared with TAPP technique of inguinal hernia repair.

Ours is the first randomized study evaluating the effect of laparoscopic groin hernia repair on sperm count and anti-sperm antibody level. We have found that there was no decrease in the sperm count and also none of the patients developed significant anti-sperm antibody following laparoscopic repair at 3 months post-operatively. Also both TAPP

and TEP were comparable. The explanation for this may be that during laparoscopy there is minimal handling of the vas deferens and cord structures, hence the blood testes barrier may remain intact and thus the patients did not develop any anti-sperm antibody.

Sexual dysfunction in patients of inguinal hernia patients is a known complaint and has been attributed to factors such as pre-operative pain associated with inguinal hernia and the increase in the intensity of the pain and the dragging sensation and engorgement of cord vessels during sexual activity. Post herniorrhaphy inguinal, genital or ejaculatory pain occurs in a small percentage of men after groin hernia repair. There are no randomized control trials comparing sexual functions in open versus laparoscopic or TEP versus TAPP. Danish hernia database study on patients undergoing groin hernia repair (both open and laparoscopic) reported dys-ejaculation in 0.1% of patients [5]. Some pain in the groin or genitals was reported during sexual activity in 10.9% and moderate to severe impaired sexual activity in 2.4% patients. In a study by Ziren et al. sexual function improved in 15% and worsened in 14% patients post-operatively [6].

In this study using the Brief Male Sexual Function Inventory (BMSFI) [13] for sexual functions we found significant improvement in all the domains of sexual functions particularly in the sexual drive and the overall satisfaction. This can be attributed to the reduction in the pain and heaviness in the groin following inguinal hernia repair. Both the techniques, TEP and TAPP were comparable in the terms of their effect and outcome on sexual functions.

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Compliance with ethical standards

Disclosures Krishna Asuri, Aamir Mohammad, Om Prakash Prajapati, Rajesh Sagar, Atin Kumar, Mona Sharma, Pradeep Kumar Chaturvedi, Shardool Vikram Gupta, Sanjeet Kumar Rai, Mahesh Chandra Misra, Virinder Kumar Bansal declares that they have no conflict of interest.

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