

Original Article**NO-SCALPEL VASECTOMY IN A CAMP APPROACH:
FOLLOW-UP, COMPLICATIONS AND COMPLIANCE**Patel Piyush R¹, Shah D K², Modi Anjali³, Mistry Sunita N⁴**Financial Support:** None declared**Conflict of interest:** Nil**Copy right:** The Journal retains the copyrights of this article. However, reproduction of this article in the part or total in any form is permissible with due acknowledgement of the source.**How to cite this article:**

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Email: dranjalimodi@gmail.com**Date of Submission:** 04-07-12**Date of Acceptance:** 09-08-12**Date of Publication:** 01-09-12**ABSTRACT****Background:** This study was done to evaluate the no scalpel technique (NSV) for vasectomy in camp approach and establish recommendations for health education and special attention to issues affecting compliance to post vasectomy instructions and post vasectomy semen analysis (PVSA).**Materials and Methods:** This was a prospective study of various aspects of NSV like details of procedure, characteristics, complications and compliance rate among clients who were operated in camps organized at six Primary/ Community Health Centers (PHCs/CHCs) in Vadodara district during January 2007 to November 2008. A predesigned, pretested questionnaire was used to collect information. Follow up data was gathered on all 1000 men by home/clinic visits. PVSA was done three months post procedure at camp site.**Results:** The mean age of clients was 37.5±13.54 years and mean duration of procedure 9.61 minutes. Six patients developed post procedure complications like hematoma (0.1%), infection (0.2%), epididymitis (0.1%) and urethral injury (0.2%) while two failures were reported. Older men and men having more than two children are least likely to follow post-vasectomy instructions or report for PVSA (P<0.001).**Conclusion:** The present study confirms the safety and efficacy of No-scalpel technique as a minimally invasive approach and shows promising and equivalent results of camp approach to hospital settings for delivering Family Planning Services. Age of client and the number of children were important determinants and correlated to post vasectomy compliance. Our study underscores the need of client education in a different perspective where emphasis is on those who are least likely to return for follow-up.**Keywords:** No scalpel Vasectomy, Compliance, sterilization services in camps**INTRODUCTION**

India is the first country in the world to introduce the Family Welfare Program in 1951 still there is an unmet need of 7% for limiting

births.¹ Over the past thirty years, the Contraceptive Prevalence Rate (CPR) has increased from 41% to 56%, but the share of male sterilization has decreased from 3.2% to

1.2% in NFHS-1 in NFHS-3 respectively.^{1,2} To bridge the gap of providing permanent family planning methods for male partner, more client oriented and quality assured techniques for male sterilization like No-Scalpel Vasectomy (NSV) and its delivery to clients via alternate service delivery model of camps have been introduced.³⁻⁶ No scalpel technique of delivering vas for vasectomy is minimally invasive causing fewer complications, compared to the standard method.^{4,5}

Recent research emphasizes the need of more and better quality research on different vasectomy techniques.^{6,7} The evaluation of no scalpel technique in camps especially in scenario of developing countries is required because though the camps have the advantage and flexibility of reaching the needy at their doorsteps, the quality of care and thus the results, has always been a concern. There is also a paucity of data on factors affecting the client compliance to post vasectomy instructions for follow-up and post vasectomy semen analysis (PSVA) in camp approach scenario.

With this background, we designed the present study as a prospective study of no-scalpel vasectomy in camp approach, where all clients were followed by home visits to ascertain follow-up and actual complication rate. We also envisaged identifying issues in relation to socio-demographic profile of clients which may affect their non adherence to post vasectomy follow-up and semen analysis. Thus we hoped that this study will help us to establish, suitable strategies for making no scalpel vasectomy a success in camp approach and recommendations for health education and special attention to issues affecting compliance to post vasectomy instructions.

MATERIALS AND METHODS

The No-Scalpel Vasectomy was developed and first performed in China in 1974 and introduced to the world in 1984.⁸ We evaluated the No-scalpel Vasectomy in the camps organized to deliver reproductive health services. Camps are defined as alternate service delivery mechanism, when "operating team located at a remote facility (district headquarters/Medical Colleges/ FRUs) conducts sterilization operations at a sub-district facility, where these services are not routinely available."⁶

Study Design: This was a prospective or follow-up study of various aspects of no scalpel vasectomy like, complication and compliance to post vasectomy instructions among men operated in camps. Characteristics of clients and procedure were also noted before and during surgery.

Study participants and study duration: Clients who elected for NSV in camps in six Primary Health Centers /Community Health Centers (PHCs/CHCs) in Vadodara District of Central Gujarat State were enrolled for the study. The sample size comprised of all 1000 clients, who underwent surgery during January 2007 to November 2008.

Study Methods: The characteristics of clients, duration of procedure and follow-up were recorded in a pretested, predesigned questionnaire. Client selection for NSV was done according to standards of WHO eligibility criteria for vasectomy. Preoperative history, clinical examination and investigations were done according to standard guidelines. Counseling was done and informed consent was taken.⁹

Procedure: The operation was performed as per the standard operative technique. The technique of operation is described below: with three finger technique the vas was brought to the subcutaneous plane in median raphae at the junction of upper third and lower two thirds, lignocaine 1% was infiltrated first as a sub dermal wheel and then in to perivascular sheath. Same way opposite vas was also infiltrated. Total 3 to 4cc lignocaine was used. After bringing the vas to this area, it was fixed with extra cutaneous vas fixation forceps. Scrotal skin was punctured with vas dissecting forceps. Following it vas was dissected and brought out. After ligating with silk 1 cm piece of vas was excised and prostatic end of vas was covered with perivascular sheath (fascial interposition). Both ligated end were slipped inside the scrotum and small dressing applied.^{4,9}

Post-procedure: Post operatively each case received verbal and written standard instructions, with advice to continue to other forms of contraception for next three months and to have a semen analysis before resumption of unprotected intercourse.^{4,9} Antibiotic prophylaxis was given. Clients were advised to report immediately to the nearby PHC/CHC Medical officer if any problems occurred.

Complications analyzed were scrotal hematoma, a mass near the vasectomy site or bleeding causing a swelling under the wound in the scrotum (onset within 24 hours of surgery); wound infection, i.e. localized inflammation and tenderness with erythema or purulent discharge from the wound (onset within few days of surgery); epididymitis, i.e. tenderness over epididymis with variable onset (confirmed by ultrasonography) were noted.^{9,10,11}

Follow-up: Complete follow-up of all men was carried out by home visits by health care staff at PHCs/CHCs who were trained by the authors and data was collected through the PHCs/CHCs. Home visits were done post vasectomy procedure at 48 hrs and one week. Clients having any symptom and signs of complications were referred to Sir Sayajirao General Hospital Vadodara for management. Post recovery these clients were followed monthly for 6 months. All men were advised to come for post vasectomy semen analysis at the end of three months. Men having positive results for semen analysis at 3 months were followed monthly for PVSA till 6 months post procedure to find failure cases.

Post Vasectomy Semen analysis (PVSA): A PVSA protocol with 1 test showing azoospermia after

three months of the procedure and twenty ejaculations was maintained.^{4,9,12} The PVSA was carried out at all camp-sites where clients were operated previously. If the sample was positive, periodic testing was continued until azoospermia was achieved. Failure was considered when semen analysis report was positive (presence of either motile or dead sperms) at six month post procedure.

Data Analysis: The data was entered and analyzed with help of Excel sheet and Epi Info software. Mean and standard deviation were calculated for demographic characteristics of clients and duration of procedure. Chi-square tests were applied to establish association between clients' characteristics and compliance. The linear association between variables was further measured by Pearson's Correlation Coefficient.

RESULTS

The mean age among 1000 clients was 37.5±13.54 years. The median and mode of age of clients was 35 years. The duration of procedure was within the range of 6-17 minutes with a mean duration of 9.61±2.6 minutes. (Table 1)

Table 1: Characteristics of clients electing for NSV (N=1000)

Characteristics of clients	Mean ± 2 SD	Range
Age of client	37.5 ± 13.54 years	25-58 years
Number of children alive	2.704 ± 1.72	1-5
Age of last child alive	6.09 ± 5.95 years	1-22 years
Hemoglobin	12.29 ± 1.48 gm/dl	10.5 to 13.9 gm/dl
Mean duration of procedure (NSV)	9.614± 2.60 minutes	6-17 minutes

Majority, 94.1% clients had children less than eleven years in age. Maximum number of men had two children (47.5%), followed by three children (32.7%), four children (14.9%) and five children (3.2%). Fifty five percent men were between 31-40 years, 16.1% less than 30 years, 25% between 41-50 years and 3.9% above 50 years. (Table 2)

All clients were followed post-operatively by home visits 48 hours and one week post vasectomy. The semen analysis could be done only for men who came for clinic visit at the end of three months, while follow-up was done for all by clinic/ home visit. Among 1000 men, 353 came for semen analysis after three months as advised. But out of these 353 men, only 316 gave

their sample for analysis. The characteristics of clients in relation to their willingness for semen analysis are illustrated in Table 2.

Men, aged less than 30 years (64%), having two children (45.7%) or having children less than 5 years of age (51.7%) were most compliant for following surgeon's advice for follow-up. Similar trend was seen for semen analysis where men aged less than 25 years (62.1%) or men having two children (42.1%) or men with children less than 5 years (48.8%) showed maximum adherence to post vasectomy instructions. Older men and men having more than two children are least likely to follow post-vasectomy instructions or report for PVSA (P<0.001).

Table 2: Relation of characteristics of clients of NSV to their semen analysis

Characteristics of NSV clients	Gave sample for semen analysis (PVSA)*		Came for PVSA		Total (%)
	Yes (%)	No (%)	Yes (%)	No (%)	
Total	316 (31.6)	684(68.4)	353 (35.3)	647 (64.7)	1000(100)
Age of last child †					
< 5 years	231 (48.8)	243(51.2)	245 (51.7)	229 (48.3)	474 (100)
6-10 years	82 (17.5)	386(82.5)	102 (21.8)	366 (78.2)	468 (100)
11-15 years	1(2.3)	43(97.7)	3 (6.9)	41 (93.1)	44 (100)
16 years and above	2 (14.3)	12 (85.7)	3 (21.4)	11 (78.6)	14 (100)
	$\chi^2 = 18.62$; df=1; P < 0.001		$\chi^2 = 15.65$; df =1;P < 0.001		
Number of Children					
One	6 (35.3)	11 (64.7)	7 (41.1)	10 (58.9)	17 (100)
Two	200 (42.1)	275(57.9)	217 (45.7)	258 (54.3)	475 (100)
Three	76 (23.2)	251(76.8)	90 (27.5)	237 (72.5)	327 (100)
Four	28 (18.8)	121(81.2)	32 (21.5)	117 (79.5)	149 (100)
Five	6 (18.7)	26 (81.3)	7 (21.8)	25 (78.2)	32 (100)
	$\chi^2 = 48.7$; df=4; P < 0.001		$\chi^2 = 46.3$; df=4; P < 0.001		
Age of client §					
25-30 years	100 (62.1)	61 (37.9)	103 (64)	58 (36)	161 (100)
31-35 years	137 (51.9)	127(48.1)	142 (53.8)	122 (46.2)	264 (100)
36-40 years	59 (25.9)	227(74.1)	79 (27.6)	207 (72.4)	286 (100)
41-45 years	16 (9.4)	155(90.6)	22 (12.9)	149 (87.1)	171 (100)
46-50 years	3 (3.8)	76(96.2)	5 (6.3)	74 (93.7)	79 (100)
Above 51 years	1 (2.6)	38 (97.4)	2 (5.1)	37 (94.9)	39 (100)
	$\chi^2 = 207.04$; df=2; P < 0.001		$\chi^2 = 166.25$; df=2; P < 0.001		

*353 men came for follow-up but 37 did not give sample for PVSA.

† chi square calculated with Yate's correction ; equal age groups of 10 years created by joining the row values to apply statistical test.

§ To apply statistical tests, equal age groups of 10 years created by joining the row values.

Table 3 Complication rate among NSV clients in camp approach (N=1000)

Complications*	N (%)
Hematoma	1 (0.1)
Infection	2(0.2)
Epididymitis	1(0.1)
Urethral Injury	2(0.2)
Total	6(0.6)

* All men were followed by home-visits to ascertain development of complications post procedure.

In the current study, a complication rate of (0.6%) was found during the subsequent follow-up. (Table 3) The complication rates were low even in camp approach. One case developed Hematoma that was treated with tight scrotal bandage along with serratiopeptidase, analgesic and antibiotics; two cases developed wound infection that was managed with antibiotics and analgesic; one case developed epididymitis,

treated with scrotal support, analgesic and antibiotics. Two cases had urethral injury at the base of the penis which was managed with per urethral Foley's catheter for three weeks. All the cases that developed complications were managed conservatively at Sir Sayajirao General Hospital, Vadodara which is a government tertiary health care centre.

One complication encountered in our study was urethral injury at the base of the penis. This might be probably due to higher site of puncture and small scrotal size. Both cases recovered by conservative management. This complication could have been avoided by taking proper care during surgery. Out of 316 clients who underwent semen analysis, a failure rate of 0.63% was recorded as two clients were positive after six months of procedure.

The current study underscores the utility of non-scalpel technique of vasectomy and shows promising and equivalent results of camps

approach to hospital settings for delivering Family Planning Services.

DISCUSSIONS

The permanent male sterilization method, vasectomy, is ideal choice of contraception for couples who have completed their family as the procedure is much simpler technically and safer as compared to tubectomy. The camps address the issue of large demands of unmet need for limiting births in underserved areas which are not usually endowed with specialized services.⁶ Thus no scalpel vasectomy in camps helps to deliver quality services to people opting for permanent methods of contraception irrespective of their proximity to institutionalized services.

The current study was conducted among men who elected for no scalpel vasectomy in camps/fixed day surgeries organized at six PHC/CHCs in rural areas of Vadodara District. The mean age of clients was 37.5 years with a range of 25 to 58 years. The average number of live children among these men was 2.7 (range 1-5 children) while the mean age of last alive child was 6.09 years (range 1-22 years). McDonald document similar findings of clients' age 37.5 years and mean number of children 2 respectively.¹¹ The mean duration of procedure in present study conducted in camps was 9.6 minutes which was similar to the findings of Kumar and Kaza et al in a hospital in Delhi.¹⁰ (Table 1)

The results from the present study indicate that the overall rate of compliance (35.3%) to post vasectomy instructions to return for PVSA was low. The willingness for giving samples for semen analysis was even lower and 31.6% only. Similar studies show a non-compliance rate of 34% to 42% among vasectomy clients.^{11,14-15}

PVSA compliance rates were correlated to age and number of children. Very strong negative correlation was found between age of client and adherence to post vasectomy instructions ($r = -0.953$; $t = 4.51$ and $p < 0.02$). Similar trend was seen with increasing age of last alive child. Perhaps this was because as the client's age will increase, so will his child's. The number of children the client had, was also very strongly correlated to compliance ($r = -0.93$; $t = 4.37$ and $p < 0.05$) and men having more children were less likely to follow-up post procedure.

Thus the present study suggests that younger men and men having two children are most likely to come for post vasectomy checks for azoospermia. Another study in Canada shows that noncompliance is associated with older age and lower occupational class. Study by Maatman et al also shows correlation between age and compliance rates.^{11,14}

The low compliance rate reported in present and similar studies done elsewhere, calls for in depth research to develop appropriate strategies like patient education, counseling and special attention to those clients who are least likely to follow up.

For ascertaining the success of a new surgical technique, adequate and timely follow-up of all clients is necessary to know the actual complication rate. All 1000 clients were followed post surgery by home visits to find actual complication rate. The complications developed were minimal and minor. Out of 1000 cases operated, total six (0.6%) persons developed complications; one developed (0.1%) hematoma, two (0.2%) reported wound infection, one patient (0.1%) had epididymitis while two (0.2%) suffered urethral injury. (Table 3) Complication rate was lower than similar studies which report a complication rate in the range of 1.4% to 9.6% among NSV clients.^{11, 13} The study by Kumar et al conducted in a tertiary level health care center shows very low rate (0.17%) of complications when no-scalpel technique was used to deliver vas.⁹ A failure rate of 0.63% was found among 317 clients who came for PSVA in the current study. The findings were similar to other authors.^{11,13}

The complication and failure rate from this study is comparable to other studies done in private clinics or hospital settings in developed countries where the results are highly promising. Thus the complication rate of delivering vas by no scalpel technique can be minimal in surgeries done in camps if all the standard protocol and guidelines are followed.

Decadal follow-up of vasectomy clients is the need of the hour and studies are needed to find long term outcome of this procedure.

As the camps need to be continued till adequate institutionalized services are available to people residing in peripheral areas, the low post no scalpel vasectomy complication and failure rate found in our study answers the issue of care

provided in camps which is inspiring for the future of our Family Welfare Program.

CONCLUSIONS

The present study underscores the safety and efficacy of No-scalpel technique as a minimally invasive approach to deliver vas deferens for vasectomy in men and shows promising and equivalent results of camp approach to hospital settings for delivering Family Planning Services. The overall compliance for post vasectomy semen analysis among men is low; age and number of children being important determinants. Our study underscores the need of client education in a different perspective where emphasis is on those who are least likely to return for follow-up. In depth studies are required to develop and test strategies for ensuring adherence to post vasectomy instructions among men not likely to follow up.

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