Abstract

Introduction
No Scalpel Vasectomy (NSV) is a faster still simple and very safe procedure for permanent sterilization of men, with a low complication rate than conventional surgery. A study was conducted between June 2010 to June 2013 at the NSV Satellite Centre of Department of Surgery at LLRM Medical College, Meerut, to evaluate effectiveness and acceptance of this procedure. The objective of this prospective study was to evaluate effectiveness and acceptance of NSV in the target community.

Materials and methods
A prospective analysis of 932 vasectomies was done and data were collected on men who accepted NSV, regarding demographic information, educational status, motivating factors and surgical complications. During follow up, satisfaction with the procedure among NSV acceptors was obtained at a three point Linear scale with a range of 1-3, based on duration of procedure, pain during and after the procedure, the time required to resume work and sexual activity.

Results
The mean age of acceptors were 37 years, having average 3.25 children. The main source of information was from friends or relatives and a significant percentage of them were motivated by satisfied acceptors (47.32%). The overall complication rate was 1.5% (14/932). Most of the complications occurred during initial 200 cases (11/200 -5.5%), which significantly decreased (3/732 - 0.40%) in rest 732 cases. Among the acceptors who came for follow up, 89.26% were satisfied with the procedure.

Conclusion
NSV can be easily performed as a day care procedure. Doctors can be effectively trained during the Induction and Refresher or Retraining Courses and with gain in experience, very low and acceptable rate of complications can be achieved. This ultimately translates into a high percentage of satisfied acceptors which may be the most powerful drivers for NSV uptake in the target community.

Introduction
The Family Welfare Program in India was launched with the objective of reducing birth rates to the extent necessary to stabilize population at a level consistent with the requirements of the national economy. During the first decade, family planning focused more on improving the health of mothers and children rather than population control, but later on the achievement of demographic goals became the primary focus of the program. The Population Policy 1977 emphasized the need for an educational and motivational approach to make acceptance of family planning completely voluntary. However, in the 1980s, the time-bound, target-oriented approach was revived and efforts to encourage the use of reversible methods were initiated. The emphasis of the Reproductive and Child Health Program, including family welfare efforts, remained skewed towards female sterilization. In India, gender inequalities favour men and sexual and reproductive health decisions are usually made by them and therefore, there is a growing realization that unless men are reached, these efforts will have limited impact.

There are limited efforts to involve men in reproductive health matters still few NGOs have demonstrated that men are potentially interested in becoming more supportive and involved in reproductive health programs. An analysis of vasectomy studies stated that men who get vasectomies tend to have smaller families than women who undergo sterilization.

Despite the introduction of “no-scalpel” vasectomy and campaigns to promote male involvement in family planning and reproductive health, the acceptance of vasectomy remained negligible which is only two percent of currently married couples, nationally.

Vasectomy was introduced as a method of permanent sterilization for males in the National Family Planning Program since 1952. But recently National Family Health survey III observed that only 1% of males opted for sterilization in contrast to 37.3% of females as a method of contraception.

Non-involvement of males in reproductive health and family planning contributes to major initiatives failing to achieve their desired objectives. This fact has recently been understood as an important area among reproductive health policy makers and population researchers. Various factors found to be responsible for this low male participation were identified as loss of libido, manhood or physical weakness as well as fear of knife. Certain characteristics of NSV make it a potentially attractive option within the family planning menu. It is effective both on the individual and population levels, it is a simple procedure with few complications and it is one of the few available “modern” methods that involve men directly. Vasectomy has a pregnancy rate of zero to 2.2 percent.

Most failures can be controlled by proper follow-up and instructions to the man undergoing the procedure. In our state, the NSV is offered on a voluntary basis through NRHM, to a man of age less than 60 years, who have ever been married and has at least one child of age above one year, under the National Family Welfare Program.
Materials and methods

This work conforms to the values laid down in the Declaration of Helsinki (1964). The protocol of this study has been approved by the relevant ethical committee related to our institution in which it was performed. All subjects gave full informed consent to participate in this study.

The study was conducted in the NSV Satellite Centre of our Institution, from June 2010 to June 2013. During this period, a total of 932 NSV procedures were performed. Prior to the procedure the clients were given comprehensive information outlining the procedure, its aftercare and possible complications. History of concomitant diseases such as diabetes mellitus (DM), hypertensive heart disease, any known allergy to drugs, family history of bleeding disorders was taken. Scrotum examination was performed to exclude skin infection, hydrocele, varicocele, cryptorchidism, and scrotal mass or any previous scrotal injury or operation. Clients with hypertension, Diabetes Mellitus, abnormal scrotal conditions and bleeding disorder were excluded.

Dr. Li’s three-finger technique was used to perform the procedure, under local anesthesia using Xylocaine 2%. Complications were recorded during and after surgery. They were followed up at three months for complications and to assess the effectiveness of the procedure. Following the procedure the clients were advised to take rest for 48 hours, avoid cycling and weight lifting for seven days, wear a scrotal support for 48 hours, use temporary contraceptive methods by either of the partners during intercourse for three months or at least for 20 ejaculations, and report for an analysis of semen after three months. All the clients were given antibiotics and analgesic in form of tablets for five days following NSV.

Data were collected from each acceptor based on a questionnaire containing information on demographic characteristics, source of information, motivating factors and education status of clients. Potential clients were specifically inquired regarding awareness of NSV, reasons for accepting it as a method of permanent contraception as well as and Motivating source. Of all 932 acceptors, 540 came for follow up and satisfied acceptors, 540 came for follow up and were interviewed regarding satisfaction with the procedure and their responses was graded on a five point Linear scale with a range of 1-5, with greater satisfaction denoted by higher scores and lower scores corresponding to non-satisfaction. Satisfaction measurement was based on duration of procedure, pain during and after procedure, time required to resume work and sexual activity.

Results

A total 932 (n) men visiting NSV satellite centre in our Institution, who opted for NSV from June 2010 to June 2011 were included in the study. The mean age of acceptors was 37 years and 78.97% of these were literate. (Table 1) They were having, 3.25 children on average. Most of them 92.38% (861) were from the lower socioeconomic class and only 7.62% (71) were from middle and higher class. The reasons for accepting the procedure were completion of family, the simplicity of the procedure and early return to work. Most of them got the information from satisfied acceptors in their areas (47.32%) and mass media (21.24%). Among the rest, 18.56% got information from health workers, 8.70% from social workers and 4.18% were motivated by Doctors. (Table 2) We also conducted two community meetings in each block of Meerut district addressed by doctors and social personalities to motivate the public to accept NSV.

The most common complication was scrotal pain in 5 cases (0.54%) followed by bleeding during surgery, hematomas.
and superficial wound infection in 2 cases each (0.21% each), haematuria and lignocaine hypersensitivity reaction in 1 case each (0.1% each) reported within the first week (Table 3). Only 540 Acceptors (57.94%) came for semen analysis after 3 months of NSV and the sperm count of all of them was nil with no report of failure during follow-up period. All of these were asked to report their measures of satisfaction on 3 points Linear scale. On an average 89.26% (482) acceptors were satisfied with the procedure and postoperative events like pain, infection, early return to work and loss of libido. Only 8.56% (46) expressed equivocal opinion regarding this procedure and only 2.18% (12) were unsatisfied. (Table 4) Only one acceptor had some sexual problem following the procedure, which was found to be mainly psychological in nature on investigation. Only one client (0.11%) developed a scrotal abscess, he was hospitalized and incision & drainage was done, under I.V. Antibiotic coverage with favourable outcome.

**Discussion**

No Scalpel Vasectomy (NSV) is a novel and improved surgical procedure developed by Dr. Li Shunqiang in 1974 with intent to reduce fear of incision and complications of vasectomy. As the name suggests, the No Scalpel method does not involve a scalpel, but a small opening is still necessary.

Key to the no scalpel vasectomy, are special instruments that allow the procedure to be done with minimal manipulation of tissues. This method is considered ‘Gold Standard’ for male sterilization as its efficacy has been proved by several multicenter randomized trials. In our study, the mean age of acceptors is 37 years in our study, which is comparable to 35 years to 44.51 years reported in earlier studies. On average, each had 3.25 children, which was higher than the national average of 2.08. In an earlier study, it was observed that higher the education level lower the number of children in a family and higher the rate of acceptance of FP measures. In this study, although 78.97% of acceptors were literate but only 19.32% had studied up to secondary level, which may be the cause of higher average number of children in their family. In our study, 16.30% acceptors had studied up to high school which was much lower compared to 46% in one study of 124 NSV acceptors. There was good acceptability among Hindus (93.23%) and very poor acceptability among Muslims (6.76%) in this study, which is contrary to another study in which Hindus constituted 52% and Muslims 48%, this may be due to demographic variations. The NSV is now a standard method for permanent male sterilization all around the world. In a series of 666 NSVs, there were less than 2% complications, which included hematoma, infection, and painful sperm granulomas, epididymitis, and sexual dysfunction. In a large comprehensive survey of 179741 NSVs, there were less than 2% complications, which were due to postoperative pain and infection. There are fewer complications and less pain in NSV than in the conventional method. In a large comprehensive survey of 179741 NSVs, there were less than 2% complications, which included hematoma, infection, and painful sperm granulomas, epididymitis, and sexual dysfunction. In a series of 666 NSVs, there were complications of hematoma (0.7%), infections (1.6%), epididymitis (5.1%), and granuloma (2.2%). A Cochrane review of two randomized controlled trials showed less postoperative scrotal pain and infection in the NSV group.

Satisfactory results can be obtained by good surgical technique and liberal use of antimicrobials. In our study, the overall rate of complication is 1.5%

### Table 3: Complications observed in the NSV (n=932).

<table>
<thead>
<tr>
<th>Complications</th>
<th>No.</th>
<th>%age</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bleeding</td>
<td>2</td>
<td>0.21</td>
</tr>
<tr>
<td>Hematoma</td>
<td>2</td>
<td>0.21</td>
</tr>
<tr>
<td>Scrotal pain</td>
<td>5</td>
<td>0.54</td>
</tr>
<tr>
<td>Wound infection</td>
<td>2</td>
<td>0.21</td>
</tr>
<tr>
<td>Scrotal Abscess</td>
<td>1</td>
<td>0.11</td>
</tr>
<tr>
<td>Haematuria</td>
<td>1</td>
<td>0.11</td>
</tr>
<tr>
<td>Hypersensitivity reaction</td>
<td>1</td>
<td>0.11</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>14</strong></td>
<td><strong>1.50</strong></td>
</tr>
</tbody>
</table>

### Table 4: Satisfaction with the procedure (n=540).

<table>
<thead>
<tr>
<th></th>
<th>Satisfied</th>
<th></th>
<th>Equivocal</th>
<th></th>
<th>Unsatisfied</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>%age</td>
<td>No.</td>
<td>%age</td>
<td>No.</td>
<td>%age</td>
</tr>
<tr>
<td>Duration of procedure</td>
<td>478</td>
<td>88.52</td>
<td>44</td>
<td>8.15</td>
<td>18</td>
<td>3.33</td>
</tr>
<tr>
<td>Pain during procedure</td>
<td>448</td>
<td>82.96</td>
<td>71</td>
<td>13.15</td>
<td>21</td>
<td>3.89</td>
</tr>
<tr>
<td>After pain</td>
<td>494</td>
<td>91.48</td>
<td>35</td>
<td>6.48</td>
<td>11</td>
<td>2.04</td>
</tr>
<tr>
<td>Return to physical activity</td>
<td>503</td>
<td>93.15</td>
<td>29</td>
<td>5.37</td>
<td>8</td>
<td>1.48</td>
</tr>
<tr>
<td>Sexual problems</td>
<td>487</td>
<td>90.18</td>
<td>52</td>
<td>9.63</td>
<td>1</td>
<td>0.19</td>
</tr>
<tr>
<td><strong>Average</strong></td>
<td>482</td>
<td>89.26</td>
<td>46.2</td>
<td>8.56</td>
<td>11.8</td>
<td>2.18</td>
</tr>
</tbody>
</table>

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which are comparable or less in comparison to other studies. In our study, we observed that the operating time, which was 15 minutes on average in initial 200 cases, later on came down to an average of 8 minutes.

Another significant observation was in terms of that, most of the complications (16/21-76.19%) occurred in the first 200 cases following which rate significantly fell down (5/21-23.8%). Both of these observations suggest that with gain in the experience of this procedure both complication and operating time decreased leading to significantly more satisfied acceptors. In the National family planning program, Vasectomy was a very popular method of sterilization during 1956 and 1980 in India with 65% of cases adopting it. By the late 1970s, however vasectomy use had begun to decline and presently the prevalence of female sterilization exceeds that of Vasectomy by a factor of 37 to 1.

Probably, the new generation of beneficiaries, are not appropriately counselled as the consenting depends on one’s understanding of the procedural requirements, limitations and alternative choices. The decision also depends on the various cultural practices and practices of the society along with fear of the procedure and a deep seated belief that the vasectomy may result in castration. The reported reasons for disapproval in 19.5% males were fear of general weakness and reduced sexual performance, which was effectively mitigated by our study, as none of the patient developed any sexual problem following the procedure.

In previous studies, it has been noticed that 97% of all men were aware, but their knowledge level was low (54.0%) and (13.0%) had no knowledge. The idea that NSV is a simple and painless procedure was most appealing to men as they are satisfied acceptors. In our study, most of the potential clients (87%) were aware regarding the need for contraception as well safety and efficacy of NSV. The main source of information about vasectomy was predominantly a friend or relative (47.32%), followed by Health care professionals and social workers (31.44%) and the mass media (21.24%) like newspaper, television, radio, etc.

Public meetings addressed by doctors and prominent social personalities also played a significant role in motivating most of them, to accept the procedure. In this study, 89.26% (482) acceptors were satisfied with the procedure and postoperative events like pain, infection, early return to work and sexual performance. Satisfied acceptors emerged as the most trusted and relied source for willingness to accept this procedure (47.32%), which was very significant in comparison to any other group of motivating source of information.

Conclusion

The NSV is an easy, safe, and effective method of permanent male sterilization. It is cost-effective and complications are low. There is less pain and the acceptors can resume normal activities in 48 hours. It does not lead to any sexual or physical weakness.

The results of our study show that meticulous surgical technique and gain in experience reduces the complication rates significantly, leading to a high number of satisfied acceptors, which ultimately proved to be the most powerful driver for potential clients to accept NSV as the method of contraception. Doctors’ participation in public awareness programs increases its acceptance among the general population.

References

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