

Role of Chemical Vasectomy by using Various Chemical Agents as a Method of Male Sterilisation

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ABSTRACT

Introduction: Chemical vasectomy being a non-surgical procedure is safe, convenient and functionally reliable, having fewer complications in comparison to surgical vasectomy. Therefore aim of present study was to develop a simple non-surgical technique of male sterility which consists of injection of chemical agents, sclerosant, inducing the obstruction of vas, through the skin of the scrotum directly.

Material and Methods: Present clinical study was carried out on the cases of benign hyperplasia of prostate, admitted in surgical wards of L.L.R Hospital, Kanpur for Prostatectomy during the period of August 1982 to June 1983. Forty five patients were classified in 3 equal groups by using three different chemical agents.

Results: Best results were achieved with 0.2ml, since it obliterated about 1 cm of vas in each case sufficient length to bring about satisfactory obliteration. Quantity more than 0.2 ml up to 0.3 ml was useful but more than 0.3 ml was not able to obliterate length of vas in proportion to quantity.

Conclusion: Best chemical appears to be 95% ethanol having better results than other two chemical agents and least complications were observed with 95% ethanol.

Keywords: Chemical Agent, Ethanol, Formaldehyde, Silver Nitrate, Vasectomy

INTRODUCTION

The burning problem of recent era is population explosion which if not controlled will keep multiplying very fast making the present figures double, triples very soon. Hence main aim before medical profession is to control with all possible effective means.

There are so many temporary and permanent methods of sterilisation and contraception, but ultimately a good permanent successful and acceptable method is required. Temporary means are not convenient all the time because most of rural folk is afraid of surgical procedures and temporary procedures are neither 100% safe nor well understood by people and ultimately leads to conception. Hence one simple, good efficient method ought to be there which is generally acceptable by people, without apprehension.

In females permanent sterilisation methods are comparatively difficult since tubectomy¹ may occasionally to follow by grave complications as shock, sepsis, haemorrhage, peritonitis and even major surgery is required. Laparoscopy also needs opening of abdomen and although less but complications still arrive. Hence vasectomy is procedure which is generally preferred over therefore used as popular method of contraception.

Elective bilateral ligation of the deferens (Vasectomy) has gained increasing acceptance as a method of men and couples seeking permanent sterilisation. In spite of reports covering side effects, vasectomy remains the only contraceptive method to men where the failure rate is at acceptable levels. For the couple this procedure appears to be of increasing attraction as simple inexpensive and reliable technique. But after all vasectomy is a surgical procedure and may sometime be associated with complications like haematoma, Orchitis etc. Moreover villagers and uneducated urban population is often fearful to accept it. In the areas where the surgical personnel and minor surgical facilities are limited, mobile sterilisation camps have to be organised. An acceptable method of male sterilisation, not requiring an operative procedure, would be of great benefit in such population control programmes. Certain risks as haematoma and infection common to all surgical vasectomy would be reduced or greatly eliminated. In addition some men refrain surgical procedure on their genitalia perhaps mistakenly associating the procedure with castration might find a non-surgical procedure more acceptable. Studies done by various authors²⁻⁴ tried surgical procedures like intra-vas device, rigid prosthetic device, clips etc. Various authors⁵⁻¹⁰ used sclerosing agents in vas of animals.

In present study we have endeavoured to develop a simple non-surgical technique of male sterility which consists of injection of chemical agents, sclerosant, inducing the obstruction of vas, through the skin of the scrotum directly.

MATERIAL AND METHODS

Present clinical study was carried out on the cases of benign hyperplasia of prostate, admitted in surgical wards of L.L.R Hospital, Kanpur for Prostatectomy during the period of August 1982 to June 1983. Healthy cases without any septic focus anywhere in the body and without any genitor-urinary

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How to cite this article: Jogendra Singh, Jagdeesh Prasad, Shahid Khan, Sajid Khan. Role of chemical vasectomy by using various chemical agents as a method of male sterilisation. International Journal of Contemporary Medical Research 2020;7(7):G3-G8.

DOI: <http://dx.doi.org/10.21276/ijcmr.2020.7.7.25>



problems except retention of urine for the first time were requested to be volunteer for the said study. Cases with the history of urinary tract infection in near past or with serotal-dermatological pathologies and genitor-urinary pathologies were forbidden. Age of the men ranged between 50-75 years and all were in good general condition.

Chemicals

Different chemical agents used for sclerosing of vas were as follows:-

1. 95% Ethanol
2. 3.6%-4% formaldehyde solution.
3. 10% Silver nitrate solution.

These were injected percutaneously in the vas deferens, with a hope of obliteration resulting from inflammation and fibrosis of vas structures. 15-42 days (2-6 weeks) following the injection biopsy was taken from that area where injection was given.

Distribution of Cases

This study was conducted on 45 cases, which were divided into three groups A, B and C according to the chemicals:

1. Group A- 15 cases, 95% Ethanol.
2. Group B- 15 cases, 4% formaldehyde solution in water.
3. Group C- 15 cases, 10% Silver nitrate solution in water.

Preparation

Part of the volunteer was prepared by shaving inguino-serotal region with upper part of thigh. Then patient was taken to operation theatre to maintain asepsis and avoid any complications, since our wards did not have good hygienic conditions. (We may try this procedure anywhere with little asepsis, as in hygienic wards, hygienically arranged camps etc.). In every case, part was painted with savlon and diluted polyvinyl iodide (Betadine) and draped.

Anaesthesia

Although this procedure does not require any anaesthesia but some patients may be apprehensive and their pain threshold may be 10%, they may require little xylocaine-1% as local anaesthetic-i.e. 1-2% in spermatic cord, 0.25-0.5 cc at the point of injection in the vas. While carrying out the above study, majority did not require any anaesthesia and remained without any pain in post-injection period. In apprehensive patients, simultaneous with painting of part, xylocaine sensitivity was done to avoid any chance of anaphylaxis. Quite a good number of cases were injected at the time of supra-pubic-cystostomy and biopsy was taken at the time of prostatectomy, when the patient was already under the effect of spinal/general anaesthesia.

Fixation of Vas

Human vas runs from testes in the scrotum, in the cord to inguinal region. During this course since the scrotal skin is very thin, same can be palpated between thumb and index finger and can easily be brought very close to scrotal skin and thus can be made prominent. Since vas is situated on the posterior-lateral aspect of spermatic cord, approach from the posterior side of scrotum for fixing the vas would be convenient.

If by the above procedure fixation of vas has been difficult then we might fix the same by passing a 20 bore needle under the vas piercing through the scrotal skin. This would prevent the slipping of vas back into the scrotum. But here we have got to use little local anaesthesia in order to avoid pain induced by needle prick. In yet other cases where above procedures have failed, fixation of vas may be done by Allis's/Babeod's forceps.

Technique of Injection of Chemical into Vas

After the fixation of vas has been done, different chemicals of 95% alcohol, 4% formaldehyde, 10% silver nitrate were injected in different group of volunteers, separately.

A 25 gauge needle is inserted in vas through the serotal skin, in retrograde fashion about 1" and away from testicular end and attempt was made to reach in the tissue of vas. Once we have pierced the vas, we make sure of its presence in vas by moving the needle transversely to scrotum and looking for its mobility (in cases only where fixation of vas has been done by thumb and indexed finger). We deposit some chemical in that segment and then go further ahead proximally and again deposit some chemical. After first insertion and injection, the needle is freed from vas but not from the scrotum and needle is reinserted proximally and some chemical is further injected in pricked segment of vas and finally is taken out. In this manner material is distributed into small segment of muscular segment of vas and chances of relatively large portion of chemical running up or down the lumen is minimised. For injection in vas tuberculin/insulin syringe was used and the total quantity of the chemical injected was roughly 0.1 to 0.5 ml in different trial groups as group A, B & C of 15 patient each. Each group is divided in 5 sub-groups of three each, which were given varying quantities of chemical i.e. 0.1 to 0.5 ml. Soon after the injection, palpatory thickness of the vas increases if the chemical has really gone in.

In the subjects who were volunteers, right vas was injected with chemical while the left vas was injected with 0.9% saline i.e. normal saline which worked as control. Not more than four minutes were required for all injections including the anaesthetic to become effective. No significant discomfort was experienced after injection and patients could resume their work or activity.

Soon after the injection, patients were given scrotal support in order to reduce the pain. No antibiotics were needed in post-injection period since all the chemicals which were used had strong antiseptic action. Mild analgesics have been prescribed (Whenever and wherever needed). 1-2 cc of 1% xylocaine was given in spermatic cord and locally where incision was planned. Careful dissection was done and biopsy was taken and submitted for macroscopic examination where the palpable thickened area of biopsied vas was measured and recorded.

RESULT

In this study the effect of percutaneous injection of various chemical agents was seen on vas deferens. It was not possible to get the young adult volunteers of fertile age group. As

an alternative procedure of chemical vasectomy was done in patients admitted in surgical wards for prostatectomy and usually they were in age group of 50-75 yrs. Total no. of cases studied here was 15 and they were divided into three groups as:-

1. Group A- 15 cases, 95% Ethanol.
2. Group B- 15 cases, 4% formaldehyde solution in water.
3. Group C- 15 cases, 10% Silver nitrate solution in water.

Otherwise in this study, chemicals injections in vas were given in 68 cases but only in 45 cases biopsy of vas was possible, as remaining 23 of them went L.A.M.A., refused biopsy or were discharged. Therefore only 45 cases have been included in study.

Part of the case was prepared and draped with all aseptic precautions as mentioned before. Local anaesthetic agent was used as needed. Vas was palpated percutaneously and fixed by thumb and index finger as stated before. After fixation intra-vas-injection of chemical as 95% ethanol, 4% formaldehyde, 10% silver nitrate solution in water, separately, was given in each group i.e. A, B & C of 15 patients each.

The study of table 1, 2 and 3 was done to find out the adequate quantity of the chemical for satisfactory obliteration of vas which can in no case be spontaneously recanalisation. Above study with all three chemicals were made into three groups, i.e. A, B, C. Out of 15 cases of each, 5 groups of 3 each were injected with varying quantity of chemicals i.e. 0.1 -0.5 ml and length of vas obliterated macroscopically.

The results of study reveal that 0.1ml of chemical was not able to bring much change in vas in all three cases and all

three chemicals. In some of these cases, merely a very small nodule was seen or palpable. Best results were achieved with 0.2ml, since it obliterated about 1 cm of vas in each case which was sufficient length to bring about satisfactory obliteration. Quantity more than 0.2 ml up to 0.3 ml was useful but more than 0.3 ml was not able to obliterate length of vas in proportion to quantity, hence the chances of spillage and peri-vas leak were more, with higher quantity of chemicals leading to irritation, pain and inflammation.

However this macroscopic study gives us just vague idea of obliteration which has been confirmed by histological examination in forthcoming observation findings. Observation of table 4 show the same results as findings of macroscopic study (macroscopic findings proved histologically). Above table explains the optimum amount of chemical to bring about histological obliteration is 0.2-0.3 ml. Quantity more than this would cause spillage and peri vas leak. However above mentioned lengths of vas should complete desired histological changes and beyond above lengths the changes started finding out (transitional part) and gradually came towards normal, as we approached normal vas while section cutting.

Observations of table 5 show us the incidences of various complications faced during the study. Maximum number of complications was found associated with 4% formaldehyde solution. Best results were seen with 95% ethanol i.e. Group A. No persistent serotal inflammation/suppuration or anaphylactic shock was observed in any case but one case out of 15 showed epididymo-orchitis and fever in post injection

Quantity of Chemicals	No. of Cases	Length of VAS obliterated macroscopically (Injected)		Control
		Length in cm	Average /Range (cm)	
0.1 ml	3	No obvious change	Less than 1	No significant change
0.2 ml	3	0.8,1.2,1.5	1.2/0.8-1.5	No significant change
0.3 ml	3	1.8,1.9,2.0	1.9/2.0	No significant change
0.4 ml	3	2.1,2.5,2.8	2.5/2-3	No significant change
0.5 ml	3	2.0,2.7,2.9	2.5/2-3	No significant change

Table-1: Showing macroscopic changes in Vas after Biopsy for finding out obliterated length using 95% ethanol

Quantity of Chemicals	No. of Cases	Length of Vas obliterated macroscopically (Injected)		Control
		Length in cm	Average /Range (cm)	
0.1 ml	3	No obvious change	Less than 1	No significant change
0.2 ml	3	0.8,1.2,1.3	1.1/1.0	No significant change
0.3 ml	3	1.4,1.6,1.5	1.5/1-2	No significant change
0.4 ml	3	1.5,1.9,2.3	1.9/1.5-2.5	No significant change
0.5 ml	3	2.1,2.0,2.4	2.2/2-2.5	No significant change

Table-2: Showing macroscopic changes in Vas after Biopsy for finding out obliterated length using 4% formaldehyde

Quantity of Chemicals	No. of Cases	Length of Vas obliterated macroscopically (Injected)		Control
		Length in cm	Average /Range (cm)	
0.1 ml	3	Hardly a nodule seen	Less than 1	No significant change
0.2 ml	3	1.0,1.4,1.5	1.3/1.5	No significant change
0.3 ml	3	1.5,1.9,2.3	2.1/2.5	No significant change
0.4 ml	3	2.5,2.7,2.9	2.7/3.0	No significant change
0.5 ml	3	2.4,2.8,2.1	2.4/2-3	No significant change

Table-3: Showing macroscopic changes in Vas after Biopsy for finding out obliterated length using 10% Silver Nitrate Solution

Agent	No. of Cases	Quantity (ml)	Length of vas obliterated	Control
95% Ethanol	3	0.1	Less than 1cm	Some inflammatory cells seen
	6	0.2-0.3	1.0-2.0 cm	
	6	0.4-0.5	2.0-3.0 cm	
4% Formaldehyde	3	0.1	Less than 1cm	Some inflammatory cells seen
	6	0.2-0.3	1.0-1.5 cm	
	6	0.4-0.5	1.5-2.5 cm	
10% Silver nitrate	3	0.1	Less than 1cm	Some inflammatory cells seen
	6	0.2-0.3	1.0-1.5 cm	
	6	0.4-0.5	2.0-3.0 cm	

Table-4: Histological obliteration of vas after injection of sclerosing chemical agent

Complications	Group-A	Group-B	Group-C
	95% Ethanol	4% Formaldehyde	10% Silver Nitrate
	(15 cases)	(15 cases)	(15 cases)
Anaphylactic shock	NIL	NIL	NIL
Fever	1	2	1
Pain	3	5	4
Haematoma	NIL	NIL	NIL
Orchitis	1	2	NIL
Epididitis	1	2	NIL
Scrotal-suppuratation	NIL	NIL	NIL
Scrotal-inflammation	NIL	2	1

Table-5: Showing the incidence of various complications in post-injection period with said three chemicals

period which subsided with anti inflammatory drugs and antibiotics. With formaldehyde (4%), incidence of pain fever, epididymo-orchitis was much more compared to other two chemicals. Five out of 15 cases had severe pain in post injection period and 2 out of these developed epididymo-orchitis of severe degree with high grade fever (with chills and rigors). In no group/case shock at the time of injection or haematoma in post injection period was observed.

DISCUSSION

Vasectomy being surgical procedure is known to be associated with complications. An effect to find out a non-surgical technique of male sterilisation would eliminate or decrease chances of complications. We have used three different chemicals viz. 95% ethanol, 4% formaldehydes and 10% silver nitrates as sclerosant for human vas. They were injected percutaneously eliminating the surgical part of vas ligation.

Ethanol is first chosen for intense investigations because of its known low toxicity, once it has been diluted in body. Several other chemical agents appeared to produce good results in animal trials as 10% silver nitrates, 4% formaldehydes, 3% sodium tetradecyl sulphate, 36% acetic acid etc. and in combination with 95% ethanol. However in our study we used three chemicals as stated before, separately. These simple compounds are easily metabolised in body, leaving no residual material to produce adverse effect. However, same should hold true for acetic acid as well. Other agents promise for future trials. Transcervical injections of quinacrine into the fallopian tubes have lead to sterility in women. Studies using methylene blue dye in cadavers seems to infiltrate vas without extensive run off.

For this study healthy cases (45) were selected and divided into 3 groups of 15 each for each chemical viz-95% ethanol, 4% formaldehydes, 10% silver nitrate solution. After the preparation and aseptic precautions, vas was palpated and brought to skin and injection of chemical agents on right side and of normal saline (0.9% NaCl) on left side in equal quantity, in some case was given. Each major group was subdivided into a group of 3 patients each. This was in order to find out the optimum quantity of chemical to be injected for desired obliteration of vas. Anaesthetic agents as 1% xylocaine was used as needed. Varying quantity of chemicals from 0.1 -0.5 ml was used. Little discomfort as headiness has been reported by good number of cases post injection. Slight redness for 4-6 hours at the site of injection in scrotum was seen in majority but there was no desquamation, skin loss, discomfort. It has not been seen at all and patients returned to their work immediately after injection.

Examination of scrotum after injection revealed non tender nodule of about 1 cm in size at the site of injection which later became a less distinct fusiform enlargement of vas deferens. Epididymitis sometime occurs after routine surgical vasectomy. Thus, far, this has been occurred in only three subjects, not leaving symptoms and signs suggestive of proctitis (where proctactomy was not done till 3-6 weeks after injection).

Results from the study for optimum quantity of chemical revealed that the cases injected with less than 0.1 ml, chemical did not show required histological changes in vas i.e. which was required for obliteration. Our study shows that most suitable and optimum quantity is 0.2 ml-0.3 ml. This quantity was able to obliterate 1-2.5 cm of vas varying with different chemicals. Relatively more length of vas was

destroyed with 10% silver nitrate. However 0.2 ml was the best because in future if the patient wants recanalisation, that small perfectly obliterated segment of vas may easily be resected and it can be re-anastomosed without any trouble while with higher quantities as 0.3 ml-0.5 ml, a relatively major part of vas is destroyed i.e.2-3 cms. Secondly so much (table 1-4) may not be able to travel through the tissue of the vas and hence the chances of peri-vas spillage increase and thus chance of complications as haematoma/scrotal skin excoriation/inflammation, difficulty in future resection and recanalisation increase. Even the discomfort to the patient also increases to the considerable extent. During evaluation for infertility used 0.25 ml of diluted Feno griffin-60 (Squibb) which as entirely injection into human of a surgically exposed patient human vas deferens in a living patient which on X-ray revealed a segment of vas slightly less than 3 cm. This also indicates towards 0.2 ml being the optimum dose for injection, especially when presence of tip of needle cannot be ascertained that it is human /wall of vas.

Results achieved after the histopathological examination of the macroscopically thickened vas resulting from different chemical injections were carefully observed for obliteration. In all 89% cases revealed blockage and 11% just reduction in human size (i.e. with patient human). Previous study¹¹ do not indicate towards such a high rate of failure. Failure in our study may be because of two reasons: (1) the cases that were injected with sub-optimal dose of 0.1 ml, were included in study technique requires skill with expertise and experience hand comes through practice. To eliminate the later error starting cases that were just injected for the purpose of practice were not included in the study.

As regards complications least number were observed associated with 95% ethanol. Although, slight temporary inflammation in post-injection period is likely which disappears itself but no case from group A showed persistent inflammation while 2 cases from group-B and a single case from group-C revealed it. The incidence of pain, fever, epididymo-orchitis¹² was most in group-B where 5 patients had severe pain post injection and two out of these soon developed severe epididymo-orchitis with fever, chills and rigors. However a single case of group -A had moderate Orchitis 4-5 days following the injection. With silver nitrate 10%, there was only slight pain but no complications otherwise.

Hence in nut-shell, the best chemical appears to be 95% ethanol having better results than other two and least complications were observed with 95% ethanol. Next are the 10% silver nitrate and then 4% formaldehyde which being associated with pain and expected complications, should not be used as sclerosant.

The most important advantage of vaso-injection opposed to vasectomy is that the risk of postsurgical haemorrhage appears to be essentially eliminated.¹³⁻¹⁴ This is the most common immediate postoperative complication and is reported to occur in frequencies of 0.3% to 5.9%.

Possible Limitations to Chemical Vasectomy-

1. At present, this procedure appears to be permanent. No evidence of recanalisation of the vas or return of fertility in animals or humans who were successfully made sterile has been seen. However, these observations have been taken place over a short period of time compared to the human reproductive life. This must be confirmed with longer studies in more human volunteers.
2. The possibility of surgical reversibility is not known. It is anticipated that the amount of vas affected would depend on volume and nature of the material injected.
3. Failure rate of surgical vasectomy varies with the operation and technique. Similar limitations would undoubtedly apply to this method.
4. Long term adverse effects of all methods of vas occlusion need carefully controlled studies.

CONCLUSION

The results of present study conclude that it is completely a non-surgical procedure. It is safe, convenient and functionally reliable. It is very cheap. Procedure can be used in people who frain surgical procedure. Chances of complications as compared to surgical vasectomy are much lower and eliminated. Patients after this procedure may easily resume their work, immediately to earn bread and butter. No problem like stitch removal for people. 95% ethanol is most suitable for use as sclerosant and is associated with least number of complications. Next is 10% silver nitrate solution followed by 4% formaldehyde. Degree/extent is better with 95% ethanol than other two chemicals. Use of 4% formaldehyde as sclerosant should be restricted till further studies since maximum complications were associated with it. The length of the vas destroyed depends upon the amounts of the chemical injected.

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Source of Support: Nil; **Conflict of Interest:** None

Submitted: 31-05-2020; **Accepted:** 18-06-2020; **Published:** 14-07-2020