Does the use of video improve patient satisfaction in the consent process for local-anaesthetic urological procedures?

by

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DECLARATION

I, *Allison Louise Moore*, hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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ABSTRACT

Purpose

To assess patient satisfaction with the use of Portable Video Media (PVM) for the purpose of taking informed consent for common urological outpatient procedures performed under local anaesthesia.

Methods

Patients undergoing the following procedures were approached for recruitment: flexible cystoscopy with or without biopsy, transrectal ultrasound-guided prostate biopsy or flexible cystoscopy with insertion or removal of a ureteric stent. Audio-visual media were developed for each procedure, with each script translated from English into isiXhosa and Afrikaans. The study involved a cross-over for each patient between Standard Verbal Consent (SVC) and PVM consent, with each patient randomised to start with SVC or PVM consent. Each of these consent-arms were assessed via a questionnaire.

Results

60 patients completed participation, with PVM as the first exposure for 28 patients and 32 patients receiving SVC as their first arm of the study.

When comparing the overall satisfaction between SVC and PVM consent (the total scores out of 18 for the questionnaire), patients scored significantly higher for PVM consent (M = 16.3 ± 2.4) compared to SVC (M = 15.4 ± 2.9) (p = 0.002). 92% of the total patient sample preferred PVM consent.

Conclusion

PVM proved superior to SVC in improving satisfaction in the consent process for common outpatient urological procedures performed under local anaesthesia.

Keywords: video media. Informed consent. Patient satisfaction

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Abbreviations

PVM:	Portable Video Media
SVC:	Standard Verbal Consent
RCT:	Randomised controlled trial
DVD:	Digital video disc

THESIS

Chapter 1: INTRODUCTION

Barriers to effective communication between healthcare providers and patients in South Africa include a diverse linguistic environment and poor levels of literacy [1]. The concept of "unproductive patient-provider interactions" in South Africa has been described [2]. Without good communication, the conditions required for informed consent will not be met. With this in mind, the hypothesis for this study was developed: that traditional verbal consent leads to inadequate patient comprehension of the perioperative discussion and reduced patient satisfaction in comparison to novel means of taking informed consent.

Since the 1970's surgeons have investigated the limitations of traditional verbal consent. The evidence pointed to suboptimal information delivery proven by poor patient recollection of perioperative information [3,4].

With the recognition of the limitations of verbal consent came the development of tools to attempt to improve this. From the 1980, studies are published that utilise written and/or audio-visual media for this purpose. Wallace developed information booklets for patients undergoing minor gynaecological surgery and noted improved patient knowledge of the procedure with this intervention [5].

In the field of Urology, trials investigating the adequacy of informed consent are found from the 1990's. Saw and colleagues utilised written information in addition to verbal consent in preparing patients for transurethral resection of the prostate [6]. Patient recall of the potential for retrograde ejaculation was poor: 18% of patients had no recall of this risk, while 75% required prompting prior to recall.

Subsequent research is focused on the use of multimedia tools in an effort to improve the informed consent discussion. A pilot study of video-assisted informed consent was performed by Sahai and colleagues in patients undergoing laparoscopic urological procedures [7]. Patients were given the option of viewing a video in addition to verbal consent and an information leaflet. This was neither a randomised nor controlled trial. Of those who chose to view the video, 95% reported it to be useful and the mean satisfaction scores for this group were high. These findings made clear the need for further research in the form of randomised controlled trials (RCTs).

Work in the application of audio-visual media to the urological clinical setting has overwhelmingly been focused on utilising video as a decision-aid in prostate cancer screening and treatment [8]. There is a paucity of research in the use of video in consent for urological surgeries. Winter and colleagues performed an RCT investigating portable video-media (PVM) in consenting patients for cystoscopy and ureteric stent insertion [9]. Significant improvements in the participants' retention of information were achieved with the use of PVM. Eighty percent of their study participants preferred PVM to standard verbal consent, although no difference was demonstrated in patient satisfaction scores between the two groups.

In the developing-world setting, no RCTs in this field were identified. Multimedia tools have, however, been developed to improve informed consent for adults participating in clinical trials in low socioeconomic settings [10-11]. Afolabi and colleagues developed a multimedia digital video disc (DVD) to consent adults for recruitment into a clinical trial in the Gambia in a region with low levels of literacy [10]. The DVD resulted in a statistically significant improvement in the participants' understanding and retention of information in comparison to verbal informed consent. In contrast, in a study performed in Ecuador, comprehension of the content delivered regarding a clinical trial was not statistically different

between video-delivery and standard verbal information delivery in potential trial participants with low levels of education [11].

A need was identified for research into the application of video for consent of urological procedures in the developing-country setting and, more specifically, the outpatient setting. Office-based urological procedures are high volume services at South African public hospitals. With 20% of South African adults being illiterate [1], written information is an inappropriate stand-alone tool to augment the consent discussion in this context. Video has the potential to overcome these deficiencies.

This study's primary aim was therefore to assess if PVM, in the patient's first-language, improved patient satisfaction with the means by which they consented for common outpatient urological procedures. The study hypothesis was that the use of PVM would result in improved patient satisfaction in comparison to SVC. The secondary aims in this study were to assess the benefit of patient information leaflets as an adjunct to PVM and to assess whether PVM improved patient understanding of the procedure they were due to undergo.

This trial is registered with the Pan African Clinical Trials Registry (PACTR) with identification number PACTR202010744878665. This report was structured according to the guidelines in the CONSORT checklist (Consolidated Standards of Reporting Trials) for the reporting of RCTs [12].

Chapter 2: METHODS

Trial Design:

The study was a randomised controlled cross-over trial with each patient participating in both arms of the study: PVM for consent versus SVC with a doctor. All participants also received a procedure-specific patient information leaflet.

Three outpatient urologic procedures were included: flexible cystoscopy with or without (±) bladder biopsy, flexible cystoscopy with the insertion or removal of a "Double-J" (DJ) ureteric stent, and transrectal ultrasound-guided (TRUS) prostate biopsy.

Study Participants:

Patients presenting for any of the above-mentioned procedures at a tertiary-level public hospital in South Africa were approached for enrollment. Patients enrolled were required to be older than 18 years of age, able to watch a video and able to speak at least one of the following three languages: English, isiXhosa and Afrikaans. Illiterate patients could be included: the relevant documentation was read to these patients. Patients without the capacity to give informed consent were excluded.

Randomisation:

Participants were randomised to start with either PVM or SVC as their first arm of entry into the study. Randomisation was computer-generated using Microsoft 'Excel' programme's "rand()" function [13,14].

Intervention:

A questionnaire was completed by each participant following their initial consent-process, with a second questionnaire completed following crossover. Questionnaires were designed to assess the primary and secondary outcomes: patient satisfaction, the patient's perceived level of improvement in understanding of the procedure and the usefulness of the information leaflets (see questionnaire at Appendix S1).

The questions assessing patient satisfaction were based on the validated Client Satisfaction Questionnaire 8 (CSQ-8) [15], with Likert-type scale symbols to aid patient interpretation (a 5-point Likert scale ranging from 'Dissatisfied' to 'Completely Satisfied'). Patient perceived

understanding and the usefulness of the information leaflet were assessed via ‘Yes-no' closed questions. Each questionnaire was scored out of a best possible score of 18 points. In addition, each participant was asked to choose their overall preferred method of informed-consent (PVM or SVC).

The information contained in the patient information leaflets and the scripts for the videos were developed based on information leaflets from the British Association of Urological Surgeons (BAUS) [16-18]. The questionnaires, information leaflets and scripts were developed in English by the principal investigators and translated into Afrikaans by first-language-Afrikaans doctors in the Urology department. The services of a registered South African linguistics company was used to translate the documents into isiXhosa (see English versions of patient information leaflets in the Appendix).

SVC was undertaken by the urology registrars, with no scripting provided. Most of the urology registrars involved in this study were not fluent in English, Afrikaans and isiXhosa, with the usual practice being to ask assistance from a member of the nursing staff to translate the verbal consent session. Official translators are not available in daily practice, therefore these were not provided for this study. The study did not aim to improve the quality of the SVC being performed.

The videos for each procedure included a demonstration performed on simulation models together with a presentation of the script. The PVM were presented on a laptop computer.

Sample Size:

The study sample size was calculated to achieve power of 90%. The level of significance set for this study was 0.05. The sample size was determined to achieve an effect size with a mean point-difference of 0.64 for the total questionnaire score. This resulted in a number of

54 patients for the sample size. We did not aim for equal recruitment between the individual procedures as we analysed the data collectively.

Statistical Methods:

For the statistical analysis, the differences between patient-variables testing level of understanding for the two arms (PVM consent versus SVC) was assessed via the Chi-square test. For those categorical variables where more than 20% of expected cell counts were less than 5, Fisher's Exact test was used. Fisher's test was also utilised to analyse the data outcomes for questions testing level of satisfaction. The Wilcoxon signed-rank test was used to compare the means of the total scores from the questionnaires for each arm following crossover.

Approvals:

The questionnaire and methodology for this study was approved by the Human Research Ethics committee of the University of Cape Town, Faculty of Health Sciences (approvals: #406/2017 and #718/2018) (see ethics approval letter in the Appendix).

Chapter 3: RESULTS

Sample characteristics:

Our sample of 60 patients consisted of 34 (57%) females and 26 (43%) males aged 25 to 93 years (see Table 1). Thirty-four participants (57%) had a flexible cystoscopy ± bladder biopsy, 13 (22%) underwent TRUS prostate biopsy and 13 (22%) underwent flexible cystoscopy with DJ stent insertion, removal or exchange. Nineteen of the 60 participants had previously undergone the same procedure prior to their enrolment in the study.

Table 1: Demographic information of study participants

Total number of participants, n=60	**N (%)**
Gender, n (%)	**60 (100)**
Male	26 (43)
Female	34 (57)
Age, years	
Mean (range)	55 (25 – 93)
Home language, n (%)	
English	35 (58)
Afrikaans	21 (35)
isiXhosa	4 (7)
Highest level of education, n (%)	
No education	1 (1)
Primary school	21 (35)
Secondary school	25 (42)
Tertiary education	13 (22)
Number patients per procedure, n (%)	
Flexible cystoscopy ± biopsy	34 (57)
Transrectal ultrasound-guided prostate biopsy	13 (22)
Flexible cystoscopy + DJ stent insertion/removal/exchange	13 (22)

Recruitment:

Period of recruitment was from August 2017 to April 2019. The study was completed on recruitment of 60 patients. Two participants were not included in analyses due to non-completion of the questionnaires after crossover (one for each of the arms of the study).

Of those patients completing all aspects of the study, PVM was the first arm of the study for 28 patients, with 32 patients receiving SVC as their first consent-process (see Appendix S2 for flow diagram).

Perceived level of understanding

There were no significant differences between the SVC and PVM consent groups with regard to the proportion of participants who (a) felt that they fully understood the risks associated with the specific procedure ($p = 1$), (b) felt they had all the information necessary to give informed consent ($p = 0.6$), and (c) had unanswered questions ($p = 0.6$) (see Table 2).

Table 2: Perceived level of understanding: Standard Verbal Consent (SVC) versus Portable Video Media (PVM) Consent

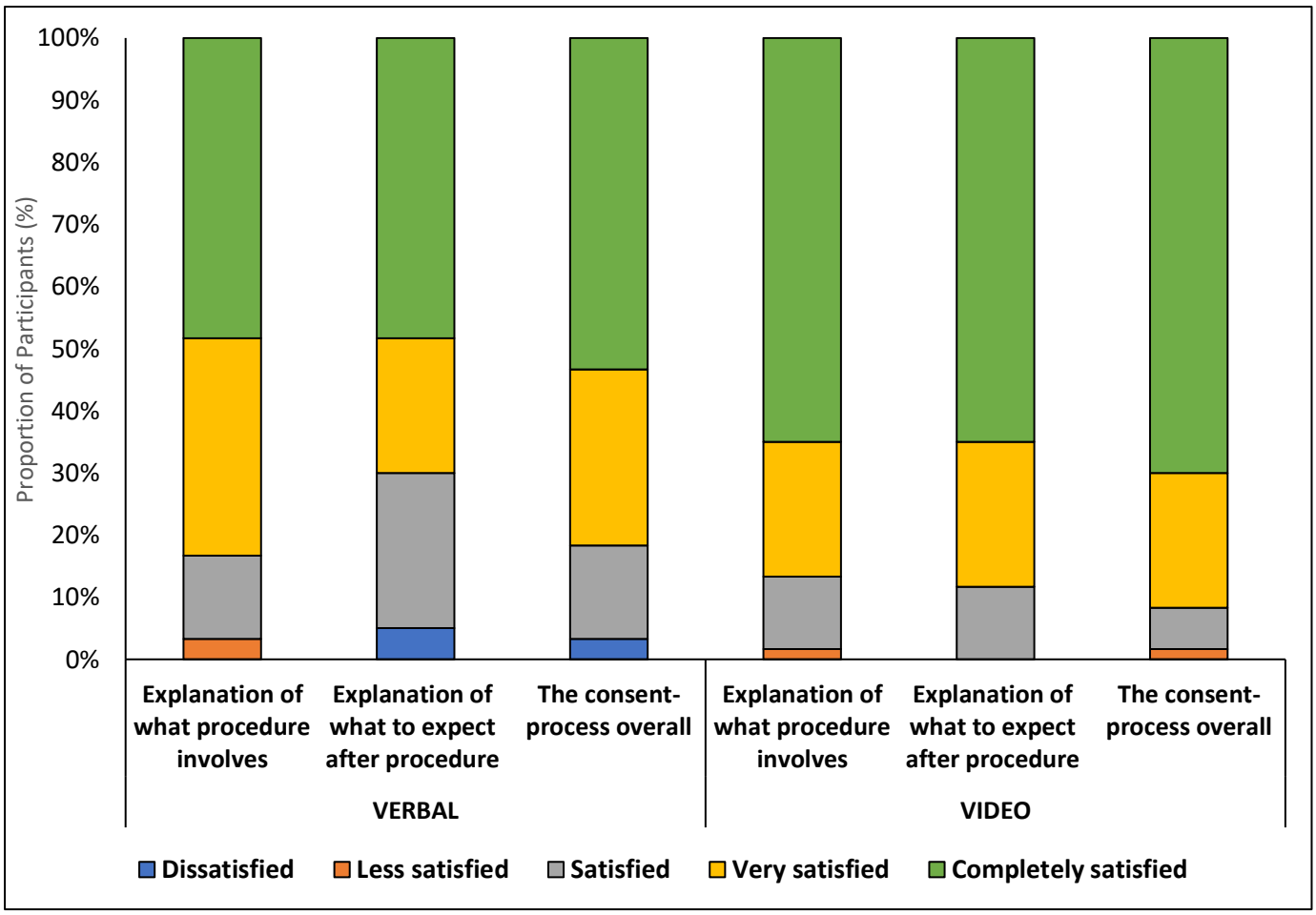
Question	**Proportion of patients answering "Yes" for SVC (%)**	**Proportion of patients answering "Yes" for PVM (%)**	***p*-value**
Do you feel you have full understanding of risks associated with the procedure?	90	90	1
Do you feel you have all the information necessary to give informed consent?	98	95	0.6
Do you have unanswered questions?	15	18	0.6

Level of satisfaction

When comparing the satisfaction levels of patients undergoing SVC versus the PVM consent process (see Figure 1), there was no difference in the level of satisfaction with (a) the explanation of what the procedure involved ($p = 0.5$), and (b) the consent-process overall, that being the patient's overall level of satisfaction with PVM consent or SVC ($p = 0.11$). There was no statistically significant difference in the level of satisfaction with the explanation of what to expect after the procedure between video and verbal consent processes ($p = 0.054$). A higher proportion of participants were 'completely satisfied' or 'very

satisfied' with the explanation in the PVM consent process (85%) compared to SVC (70%). This difference is statistically significant (p = 0.049).

Fig. 1 Patient satisfaction with verbal consent-process versus video consent-process



Overall patient preferences

When comparing the overall outcomes assessed between SVC and PVM consent (the total score out of 18 for the questionnaire, that being a combination of the scores for the subsections of 'satisfaction' and 'understanding'), participants scored significantly higher for PVM consent (M = 16.3 ± 2.4) compared to SVC (M = 15.4 ± 2.9) (p = 0.002). When asked to choose their preferred method for consent, the vast majority of participants (92%) reported preferring the PVM consent-process, whilst only 3 (5%) reported preferring SVC (2 patients did not answer this question).

Benefit of Patient Information Leaflets

All of the study participants reported the procedure-specific patient information leaflets to be a beneficial adjunct.

Chapter 4: DISCUSSION and CONCLUSION

Discussion

Gaining informed consent is a fundamental part of surgical practice. This involves ensuring that the patient understands their condition and the reason/s for the proposed treatment including risks, benefits and alternatives [19]. Successfully fulfilling the requirements for informed-consent within a busy and resource-limited healthcare setting is difficult.

The National Health Act of the Republic of South Africa states that a healthcare provider must, where possible, inform a user (the person using a health service) 'in a language that the user understands and in a manner which takes into account the user's level of literacy' [20]. Research shows that in the patient-provider interaction, only 50% of what is communicated is understood by the patient [21]. Chima, in his study performed in South Africa, found that doctors reported 'language difficulties' as the most significant barrier to obtaining valid informed consent [22].

The results of this study show that a higher proportion of participants were more satisfied with the explanations provided by PVM in comparison to SVC. The overall satisfaction score for the questionnaire was significantly higher for PVM consent ($p = 0.002$). These findings support the satisfaction portion of the original study hypothesis: that the use of PVM would result in improved patient satisfaction in comparison to SVC.

The primary outcome of this current study was the improvement in patients' satisfaction scores. Basing the questionnaire on the CSQ-8 improved the external validity of this tool.

Study results are in keeping with most of the literature, showing a significant improvement in patient satisfaction with informed consent with the use of PVM. Huber and colleagues, in preparing patients for radical prostatectomy, found that multimedia-supported education significantly improved patient satisfaction with the preoperative session: 69% of patients completely satisfied versus 52% reporting complete satisfaction with standard education [23].

A secondary outcome of this current study was the benefit of a patient information leaflet, as an adjunct to the consent-process. The study showed that in this patient sample, the information leaflets were perceived to be beneficial. The use of information leaflets with PVM was the focus of research performed by Joseph and colleagues for patients undergoing ureteric stent insertion [24]. In the study by Joseph and colleagues, the information sheets provided education regarding stent-irritation symptoms post procedure. The outcome in this study was re-presenting to an emergency department for stent irritation. Use of information sheets together with PVM resulted in a reduction in numbers of patients re-presenting with stent-symptoms. This study demonstrates an alterative use for information sheets, not for the purpose of taking informed consent.

Knowledge improvement through PVM was an additional component of our hypothesis. The scores for questions which focused on the knowledge-component of the questionnaire showed no significant difference between PVM consent and SVC. These questions were not derived from a validated source.

These results differ from the majority of the literature, with published studies mostly showing better comprehension of a procedure through the use of video-media for consent. These studies were based on more complex surgical procedures in comparison to the local-anaesthetic, minor procedures included in the current study. This may have influenced the difference in outcomes seen in the current study.

In consenting patients for radical prostatectomy, an interactive PowerPoint presentation produced significantly better knowledge scores (78% versus 57%) regarding the surgical procedure in comparison to SVC [25]. In this study, Gyomber and colleagues used non-validated questions to test comprehension.

A recent publication from Saglam and colleagues similarly showed significantly higher scores for patient comprehension when adding an educational video to the verbal informed consent-process for bariatric surgery [26]. This randomised controlled trial by Saglam and colleagues was noted to be a pilot study, with the questionnaire used developed specifically for that study. Validated knowledge-testing tools are, therefore, still lacking in the literature.

The results from the current study are generalisable to other developing countries: the sample is of varied ages and includes a diversity of languages. Level of education is higher in this sample than the South African national rate: 63% of participants had completed secondary school in comparison to the population average of 30.9% [1]. These results may, therefore, not be generalisable to a less educated population.

Potential sources of bias were observer bias and the lack of blinding. Observer bias may have resulted in the participants over-scoring the doctors for SVC. Additionally, questionnaires were on occasion administered by the same doctor taking verbal consent, although this was in a small proportion of participants.

In summary, the results of this study support the use of PVM in the consent-process due to a higher proportion of participants being more satisfied with this means of informed consent. The implementation of PVM for consent in Urology departments could have other benefits including less need for translation services and more efficient running of outpatient clinics.

Conclusion

This study finds that a significantly greater proportion of the study participants reported higher levels of satisfaction with PVM for informed consent in comparison to SVC for the urological procedure they were due to undergo. As a secondary outcome, the information leaflets were considered helpful. There was no statistically significant difference in patient reported comprehension of the consent process.

This current study uniquely contributes to the literature by demonstrating improved satisfaction with the use of PVM for procedures performed in the outpatient-setting under local anaesthetic. We therefore recommend that Urologists consider developing PVM to assist in the consenting of patients for these surgical procedures.

Further research would be best focused at utilisation of validated means of assessing outcomes. Correlation analyses would benefit our understanding of the relationship between patient comprehension and satisfaction.

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APPENDICES

Supplementary Figure S1: Questionnaire

Start time for questions: End time for questions:

Procedure: Flexi +/- biopsy Flexi + stent insertion / removal / exchange TRUS Prostate Bx

Hosp. no.: _____ Age: _____ D.O.B: _____

Please circle as appropriate

Form of consent:

Video Verbal

Which form of consent did you have first:

Video Verbal

Gender: Male Female Non-binary Prefer not to disclose

First language: English Afrikaans isiXhosa Other_____

Level of education: Primary School Secondary School Tertiary education None

1) **Have you had this procedure before:** No Yes

2) **How satisfied are you with the explanation of what the procedure involves:**

3) **Do you feel that you fully understand the associated risks:** Yes No

4) **Do you feel you have all the information necessary to give consent / make the decision to proceed or not with the proposed procedure:** Yes No

5) **Do you have unanswered questions:** Yes No

6) How satisfied are you with the explanation of what to expect after the procedure

7) Overall how satisfied were you with this consent process

8) **Did you find the accompanying procedure leaflet helpful?** Yes No

9) If this is the second time you are filling in this questionnaire –

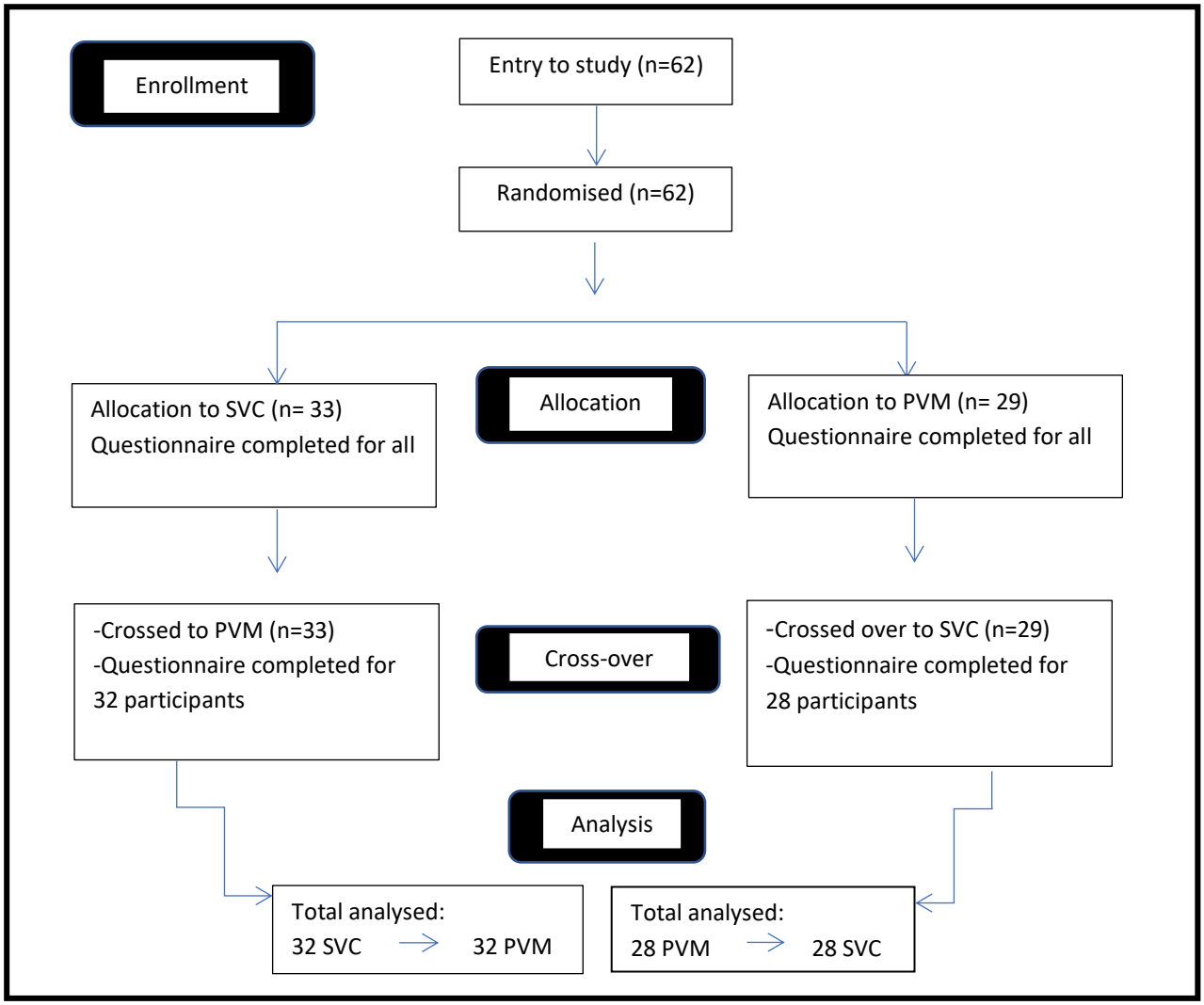
Overall which form of consent did you prefer: Verbal Video

Please state why and give any additional comments:

Why?_____
_____
_____

Additional comments: -
_____
_____
_____

Supplementary Figure S2: Flow Diagram



Appendix: Consent Form

DIVISION OF UROLOGY

Medical School – Observatory 7925
Cape Town – Republic of South Africa
Telephone: 27- 21- 406 6529
Groote Schuur Hospital:
27-21-404 6150/6105 (Office)
27-21-404 6122/4 (Clinic)
27-21-404 3344 (Ward)
Telefax: 27-21-406 6122
E-mail: shene.isaacs@uct.ac.za
Head of Department: Professor J M Lazarus
Senior Lecturers: Prof R D Barnes; Prof A R Pontin; Dr S Sinha; Dr L Kaestner

Consent to participate in a Research Study

Title of study:

<u>Does the use of video improve patient satisfaction in the consent process for local-anaesthetic urological procedures?</u>

- **You are being asked to participate in a study which looks to improve the consent process for common Urological procedures. You have been selected as a participant as you are about to undergo one of these procedures.**

- **We ask that you read this form and ask any questions that you may have before agreeing to participate.**

The Study

- **The purpose of the study is to evaluate and improve the consent process. Ultimately, this study intends to improve patient care and may be published.**

- **If you agree to be in this study, you will be asked to experience two forms of consent (in either order) and answer two brief 10 point questionnaires after each. You will also be given an information leaflet to read before the procedure.**

- **You will either first watch a short 7-minute video explaining the procedure, associated risks, benefits and what to expect after. This will be followed by answering two short questionnaires. You will then receive the same information verbally by a doctor and**

answer the same questionnaires again. You will have the opportunity to ask any questions individually before the procedure.

- **The study will not affect the treatment you receive and will not result in any known risks.**

- **The records of this study will be kept strictly confidential. We will not include any information in any report we may publish that would make it possible to identify you.**

- **The decision to participate in this study is entirely up to you. You may refuse to take part in the study at any time with no effect on your treatment or future care.**

- **Your signature below indicates that you have decided to volunteer as a research participant for this study, and that you have read and understood the information provided above.**

Subject's Name (print): _____

Subject's Signature: _____ Date: _____

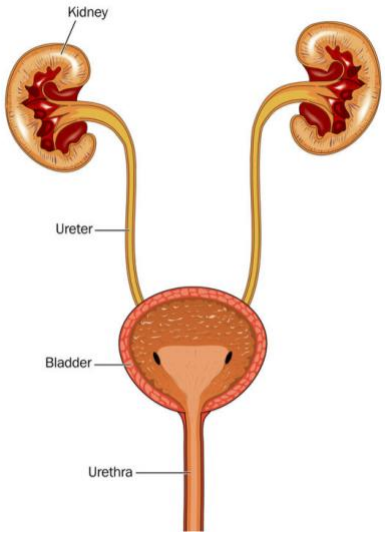
Investigator's Name (print) _____

Investigator's Signature: _____ Date: _____

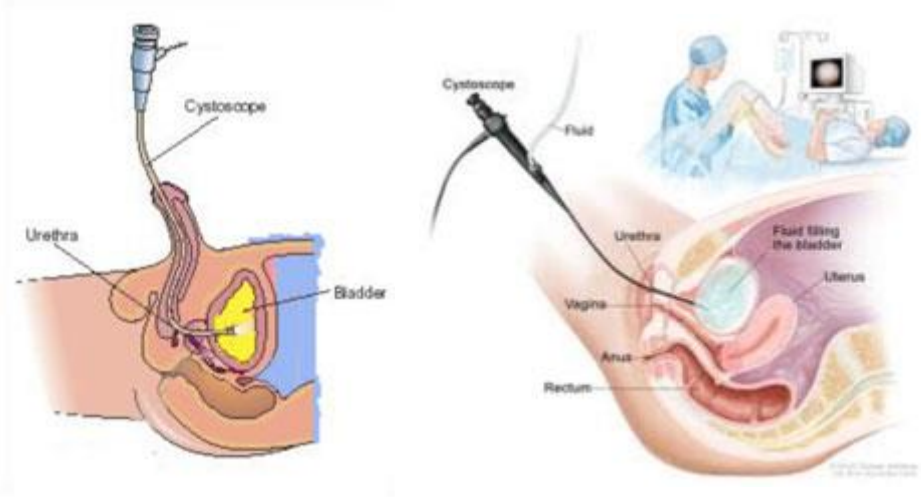
Appendix: Patient information Leaflets

Division of Urology
Groote Schuur Hospital
FLEXIBLE CYSTOSCOPY + / - BLADDER BIOPSY
Procedure-specific information for patient

Your urinary system is made up of the kidneys, ureters (the tubes that connect the kidneys to the bladder), the bladder and the urethra (the tube that allows urine to pass from the bladder out).



Urinary system



Flexible cystoscopy female and male

This procedure involves the inspection of your bladder and urethra using a small telescope, called a cystoscope attached to a camera (see images above). It is performed under local anaesthetic. Depending on what abnormality is found a biopsy or sample may be taken.

You are most likely to be undergoing this procedure to help make a diagnosis or check if a treatment has been successful. This is the only way to closely inspect the bladder and urethra. Alternatives are limited but can be discussed with your doctor at the time of the procedure.

What to expect before, during and after the procedure?

Before the procedure you will be asked to change into a hospital gown. You may be asked to give a urine sample to be tested for infection and just before starting you will be given a single dose of an antibiotic (depending on your allergies). Please tell the doctor of any significant health problems especially if you are on any “blood thinning medication” such as warfarin.

During the procedure the doctor will first clean the genital area. A local anaesthetic gel is used to numb the urethra (water pipe): this allows the cystoscope to pass more comfortably. Men sometimes find it uncomfortable when the cystoscope passes through the prostate before it enters the bladder. This discomfort should only last a few seconds.

Once the telescope is in the bladder the doctor will take a few minutes to inspect the bladder and take any biopsies if needed.

Water is used to fill the bladder during the procedure so you may get the sensation of a full bladder.

Once the procedure is completed the instrument will be removed and the results/findings and further plan explained to you. You can then pass urine if needed, get changed and ensure that you have follow-up appointments booked if recommended before you leave.

You can return to normal activities on the same day with no restrictions. We advise that you drink plenty of water (at least 2 litres per day) to help prevent infection and clear up any bleeding. If you develop any signs of infection such as high fevers and burning when urinating, extreme pain, continuous bleeding, passing blood clots or difficultly passing urine you should attend your local day hospital for review.

What are the risks?

There are risks associated with most procedures. The specific risks associated with this procedure are:

Discomfort – burning or stinging when passing urine after the procedure. This should settle in a day or two. If it persists you must see a doctor.

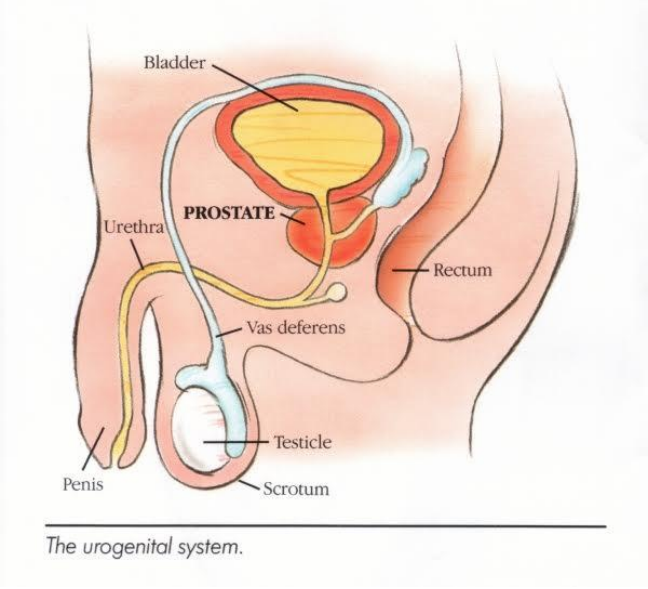
Bleeding – this is as a result of the telescope/cystoscope being passed up the urethra (water pipe). Your urine may appear blood-

stained or pink for a few days after. This should clear with time and with good fluid/water intake.

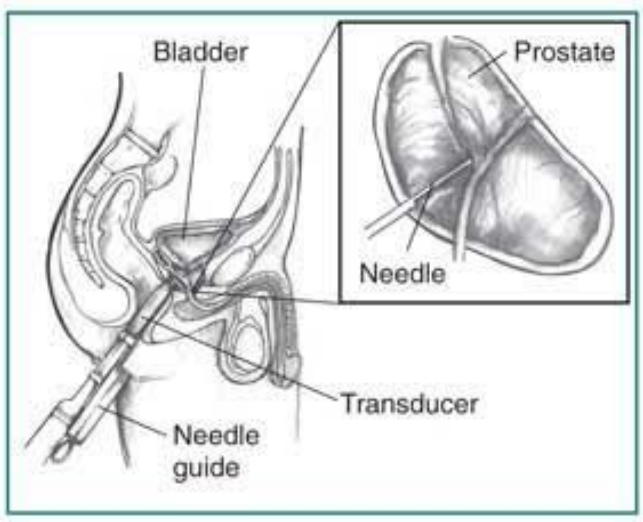
Infection – this will cause fevers and pain on passing urine. The risk is reduced by giving you an antibiotic tablet before the procedure and by drinking plenty of water after the procedure (at least 2 litres per day).

Division of Urology
Groote Schuur Hospital
TRANSRECTAL ULTRASOUND-GUIDED PROSTATE BIOPSY
Procedure-specific information for patient

The Prostate is a gland positioned under the bladder: men have a risk of developing cancer in the prostate. Biopsies are done to try determine if there is cancer in a patient's prostate or not.



The position of the Prostate



Trans-rectal Ultrasound in a Male

What does the procedure involve?

The doctor uses an ultrasound probe, inserted into the anus, to scan the prostate. Biopsies (samples) are then taken, using a needle which is inserted into the prostate.

What happens before the procedure?

You may eat and drink normally before your appointment.

If you are taking "blood-thinners" such as warfarin or clopidogrel, you must inform the doctor, who will arrange for this to be stopped before the procedure. If you are taking aspirin, you do not need to stop this.

Just before starting you will be given a single dose of an antibiotic (depending on your allergies) to try prevent infection in the prostate, urine or bloodstream.

You will be asked to sign the operation consent form, giving permission for the procedure to take place. You will be given the opportunity to ask any questions and discuss any concerns before signing the form.

What happens during the procedure?

Prostate ultrasound is usually performed under local anaesthetic.

You will lie on the examination bed on your left side with your knees bent up towards your stomach.

The doctor will start by examining your prostate with a finger-examination into the anus, and will then insert a local anaesthetic gel into the rectal passage before inserting the ultrasound probe.
The prostate biopsies (samples) will then be taken with a needle. This needle has a device that makes a “crack” sound when it is used. Typically 12 needle biopsies are taken.

Insertion of the needle is mildly uncomfortable, similar to the feeling of having a blood test. By the end of the procedure, the prostate might feel “bruised”.

The procedure takes up to 20 minutes.

What happens immediately after the procedure?

Once the procedure is completed the instrument will be removed and the further plan explained to you. You will be asked to pass urine, get changed and ensure that you have follow-up appointments booked (usually in 3 weeks).
Some patients require bed-rest for 24 hours after the procedure: we suggest that you avoid physically-demanding activities for 48 hours. We advise that you drink plenty of water (at least 2 litres per day) to clear up any bleeding. If you develop any signs of infection such as high fevers, extreme pain when passing stool, continuous bleeding from the anus, passing blood clots in the urine or difficultly passing urine you should present to C15 at Groote Schuur Hospital for review.

Driving after surgery
The discomfort experienced due to the procedure may make it difficult for some patients to drive immediately after. If you do decide to drive, it is your responsibility to make sure you feel fit to drive.

What are the risks?
There are risks associated with most procedures. The specific risks associated with this procedure are:

Bleeding –Your urine may appear blood-stained or pink for a few days. This should clear with time and with good fluid/water intake. At worst, patients can develop clots in the urine and blocking of urination.

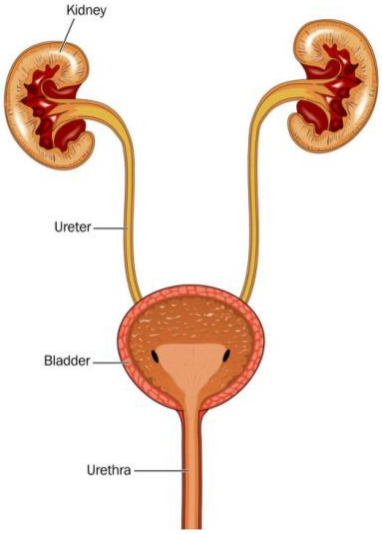
Infections – urine infections can cause fevers and pain on passing urine. The risk is reduced by giving you an antibiotic tablet before the procedure. Infection of the prostate or infection in the blood are rare complications.
The samples may not be adequate, and the test may need to be repeated

Patients at higher risk of problems:

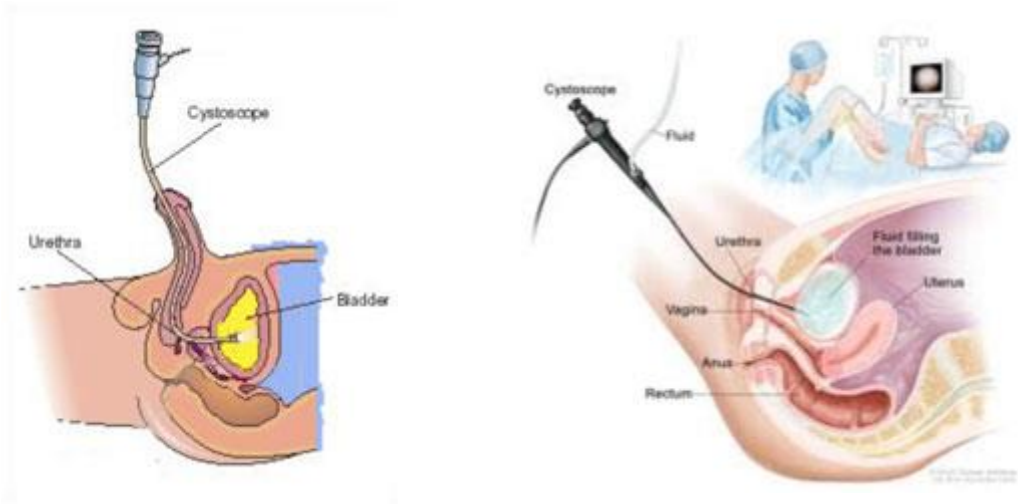
- Patients with urine catheters
- Patients with Diabetes or HIV

Division of Urology
Groote Schuur Hospital
FLEXIBLE CYSTOSCOPY + STENT RELATED PROCEDURE
Procedure-specific information for patients

Your urinary system is made up of the kidneys, ureters (the tubes that connect the kidneys to the bladder), the bladder and the urethra (the tube that allows urine to pass from the bladder out).



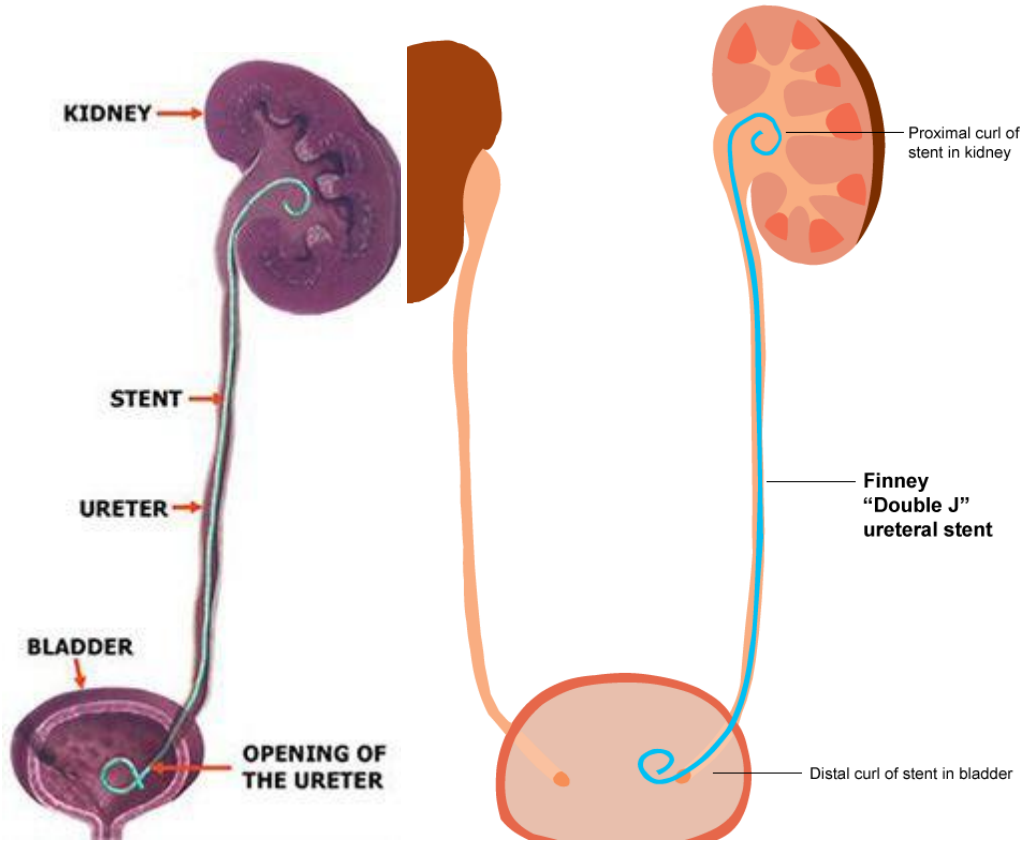
Urinary system



Flexible cystoscopy female and male

This procedure is a flexible cystoscopy and either a stent insertion, change or removal. The procedure involves the inspection of your bladder and urethra using a small telescope, called a cystoscope and the insertion, change or removal of a soft plastic tube, called a ureteric stent that is placed between the kidney and the bladder.

It is most commonly performed under local anaesthetic. However, if the procedure proves difficult or not possible under local anaesthetic it may require a further attempt under general anaesthesia. This will be discussed with you at the time.



Why has your doctor advised you to have this procedure?

You are most likely undergoing this procedure for the following reasons;

- Stent insertion or change
    - To help relieve a blockage within the ureter/s. This may be from a stone or a narrowing (stricture). The stent will help relieve the pain caused by the obstruction and reverse renal impairment.
    - To prevent blockage prior to other treatment such as shock wave treatment for ureter or kidney stones.
- Stent removal
    - Where the stent is no longer required and the decision has been made to remove it.

Alternatives include observation or placement of a tube directly into the kidney through the back (called a nephrostomy). Each of these has its own risks and benefits and can be discussed further with your doctor prior to the procedure.

What to expect before, during and after the procedure?

Before the procedure you will be asked to change into a hospital gown. You may be asked to give a urine sample to be tested for infection and just before starting you will be given a single dose of an antibiotic (depending on your allergies). Please tell the doctor of any significant health problems especially if you are on any “blood thinning medication” such as; warfarin.

During the procedure the doctor will clean and drape you with sterile sheets. A local anaesthetic gel is used to numb the urethra this allows the cystoscope to pass more comfortably. Men sometimes find it uncomfortable when the cystoscope passes through the prostate before it enters the bladder. This discomfort should only last a few seconds.

Once the telescope is in the bladder the doctor will take a few minutes to inspect the bladder and then insert, change or remove the stent.

Water is used to fill the bladder during the procedure so you may get the sensation of a full bladder.

Once the procedure is completed the instrument will be removed and the results/findings and further plan explained to you. You can then pass urine if needed, get changed and ensure that you have follow-up appointments booked if recommended before you leave.

If you have had a stent inserted or changed you will be sent for an X-ray to confirm the position of the stent. This must be reviewed by the doctor before you leave the department.

What are the risks or side-effects associated with this procedure?

There are risks associated with most procedures. The specific risks associated with this procedure are:

Discomfort – burning or stinging when passing urine after the procedure. This should settle in a day or two.

Bleeding – this is as a result of the cystoscope being passed up the urethra or from the presence of the stent. Your urine may appear blood stained or pink for a few days after. This should clear with time and with good fluid/water intake.

Infection – this will cause fevers and pain on passing urine. The risk is reduced by giving you an antibiotic tablet before the procedure and by drinking plenty of water after the procedure (at least 2 litres per day).

Stent related symptoms – These are common and vary from patient to patient. They include; temporary discomfort from the tube causing pain, urgency and frequency of urination and occasional blood in the urine.

Need for a further procedure – If you are undergoing insertion or change of a stent please note that this is temporary and should not be left in place for longer than 6 months. You will therefore require a definitive procedure to treat the cause of obstruction or to change the stent.

You can return to normal activities on the same day with no restrictions. We advise that you drink plenty of water (at least 2-3 litres per day) to help flush out any infection and clear up any bleeding.

If you develop any signs of infection such as high fevers and burning when urinating, extreme pain, continuous bleeding, passing blood clots or difficultly passing urine you should attend your local day hospital or casualty for review.

Appendix: Ethics Approval Letter

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E53-46 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6626
Email: shunetta.thomas@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

12 March 2019

HREC REF: 718/2018

Dr Justin Howlett
Urology
E26, NGSH

Dear Dr Howlett

PROJECT TITLE: THE USE OF VIDEO TO IMPROVE PATIENT SATISFACTION IN THE CONSENT PROCESS FOR UROLOGICAL PROCEDURES: A SINGLE-CENTRE, RANDOMISED AND CONTROLLED TRIAL - SUB-STUDY LINKED TO 406/2017 (MMED Candidate - Dr A Moore)

Thank you for submitting your response to the Faculty of Health Sciences Human Research Ethics Committee.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30 March 2020.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

The HREC acknowledge that the student, Dr Allison Moore will also be involved in this study.

Yours sincerely

Signature Removed

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938

HREC 718/2018