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The use of portable video media vs standard verbal communication in the urological consent process: a multicentre, randomised controlled, crossover trial

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Objectives

To determine if portable video media (PVM) improves patient's knowledge and satisfaction acquired during the consent process for cystoscopy and insertion of a ureteric stent compared to standard verbal communication (SVC), as informed consent is a crucial component of patient care and PVM is an emerging technology that may help improve the consent process.

Patients and Methods

In this multi-centre randomised controlled crossover trial, patients requiring cystoscopy and stent insertion were recruited from two major teaching hospitals in Australia over a 15-month period (July 2014–December 2015). Patient information delivery was via PVM and SVC. The PVM consisted of an audio-visual presentation with cartoon animation presented on an iPad. Patient satisfaction was assessed using the validated Client Satisfaction Questionnaire 8 (CSQ-8; maximum score 32) and knowledge was tested using a true/false questionnaire (maximum score 28). Questionnaires were completed after first intervention and after crossover. Scores were analysed using the independent samples *t*-test and Wilcoxon signed-rank test for the crossover analysis.

Results

In all, 88 patients were recruited. A significant 3.1 point (15.5%) increase in understanding was demonstrable favouring the use of PVM ($P < 0.001$). There was no difference in patient satisfaction between the groups as judged by the CSQ-8. A significant 3.6 point (17.8%) increase in knowledge score was seen when the SVC group were crossed over to the PVM arm. A total of 80.7% of patients preferred PVM and 19.3% preferred SVC. Limitations include the lack of a validated questionnaire to test knowledge acquired from the interventions.

Conclusions

This study demonstrates patients' preference towards PVM in the urological consent process of cystoscopy and ureteric stent insertion. PVM improves patient's understanding compared with SVC and is a more effective means of content delivery to patients in terms of overall preference and knowledge gained during the consent process.

Keywords

informed consent, multimedia, patient education, portable video media

Introduction

Informed consent for surgical procedures is a crucial component of patient care. It is a well-established practice between the surgeon and the patient; however in practice, it often fails to fulfil its purpose particularly in the emergency setting. The National Health and Medical Research Council of Australia and General Medical Council of the UK have detailed guidelines on informed consent. Informed consent involves ensuring the patient understands the nature of their condition, the risks and benefits of the proposed treatment, and alternative treatment options [1,2]. Barriers to this are multi-factorial and the time pressures of a busy surgical workload are a major hurdle to achieving appropriate consent [3]. In the current climate of increasing demand on our healthcare systems and limitations of resources, there is a distinct danger of compromising patient care particularly surrounding the informed consent process. The process of obtaining informed consent can be inconsistent and often inadequate and this has been shown to be linked to worse health outcomes for patients [4]. Patient understanding of their condition and treatment highly correlates with patient

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care and satisfaction and decreased postoperative complications [5,6].

Video-based education shows promising early results with the advent and ubiquitousness of portable, hand-held, mobile media devices. The portability of these small devices lends itself for easy use within a busy hospital environment. Several studies have shown that video-based patient education, leads to better patient comprehension and satisfaction and reduced patient anxiety during the consent process [3,7–17]. These studies have all been limited by their design (single centre, no control group, small sample sizes) and to date no multi-centre randomised controlled trial has been performed to the author's knowledge. Many urological procedures, in particular cystoscopy, are standardised, technical procedures, which make video-assisted education more feasible.

The present randomised study aimed to determine if video-based education delivered through portable video media (PVM)-enabled device improves patient knowledge and satisfaction regarding the consent process for cystoscopy and insertion of ureteric stent compared with conventional standard verbal consent (SVC). A secondary objective of the present study was to create an adjunct to the normal consent process and validate its appropriateness in improving patient understanding and satisfaction with the consent process.

Patients and Methods

A randomised controlled cross-over trial was performed enrolling patients presenting with acute renal colic to a major public hospital who required a ureteric stent, as determined by an accredited urology registrar. Inclusion criteria for this study were age >18 years, able to read and write in English, able to give consent, able to watch a video, and clinically indicated for acute cystoscopy and stent insertion.

Patients were randomised in an allocation ratio of 1:1 to receive information via PVM or SVC. A validated questionnaire, the Client Satisfaction Questionnaire 8 (CSQ-8; maximum score of 32) assessing patient satisfaction was then completed. This was followed by a specific true/false questionnaire (multiple choice questions [MCQ]; maximum score of 28) assessing understanding of the critical components of a cystoscopy and ureteric stent insertion. The groups were then crossed over to receive the alternative information delivery method and the questionnaires re-tested. Patients were asked to give their overall preference at the conclusion of both delivery methods.

Standard verbal consent involved the typical verbal interaction of a urology registrar consenting a patient for a procedure. The PVM consisted of an audio-visual presentation with cartoon visual animation presented on an iPad for the duration of 7:07 min.

Randomisation was computer generated on a 1:1 basis with questionnaires placed in sealed numbered envelope. Data was analysed using Wizard 1.5.2 and Excel for Mac 14.4.4. For continuous variables the Kolmogorov–Smirnov test was applied for normality testing. Comparisons between groups for normally distributed variables were performed with independent samples *t*-test and variables that were not normally distributed were analysed with Mann–Whitney *U*-tests. The Wilcoxon signed-rank test was used to compare group crossover results. A sample size of 80 was determined in order to power the study to detect a 1.5 point or larger difference with 90% power and $\alpha = 0.05$.

Results

In all, 88 patients were randomly assigned and completed the trial (Fig. 1); 43 received PVM and 45 received SVC as the first intervention and then crossover was performed according to protocol. Recruitment was completed over two sites over a 15-month period (07/07/2014 to 21/12/2015). The mean patient age was 54 years and 22 (25%) patients were female and 66 (75%) male. The mean SVC time was 4.27 min. There were no significant differences in the demographic features of the two groups (Table 1).

Effect of the Intervention

A statistically significant 15.5% increase in understanding, as assessed by the MCQ, was demonstrable favouring the use of PVM upon first intervention (PVM 23.26, 95% CI 22.16–24.35 vs SVC 20.13, 95% CI 18.64–21.63; $P < 0.001$) (Fig. 2). There was no difference in patient satisfaction, as measured by CSQ-8 between the groups (Fig. 2). After crossover there was no difference between groups for knowledge or satisfaction (Table 2).

Upon group crossover analysis a significant 17.8% increase in MCQ score was seen when the SVC group were crossed over to the PVM arm (20.13, 95% CI 18.64–21.63 vs 23.71, 95% 22.98–24.45; $P < 0.001$). No increase in MCQ score was seen when the crossover was from PVM to SVC (23.26, 95% CI 22.16–24.35 vs 23.42, 95% CI 22.22–24.62; $P = 0.621$) (Fig. 3).

In the group, which was crossed over from SVC to PVM, there was an increase in satisfaction score of 4% (29.07; 95% CI 27.96–30.17 vs 30.27, 95% CI 29.43–31.10; $P = 0.006$). There was no significant difference in CSQ-8 scores after crossover in the group that crossed over from PVM to SVC (30.16, 95% CI 29.36–30.97 vs 30.72, 95% CI 30.2–31.3; $P = 0.06$) (Fig. 3).

A total of 71 patients (80.7%) preferred PVM and 17 (19.3%) preferred SVC.

Fig. 1 Enrolment and completion of trial numbers. T/F, true/false; pt, patients.

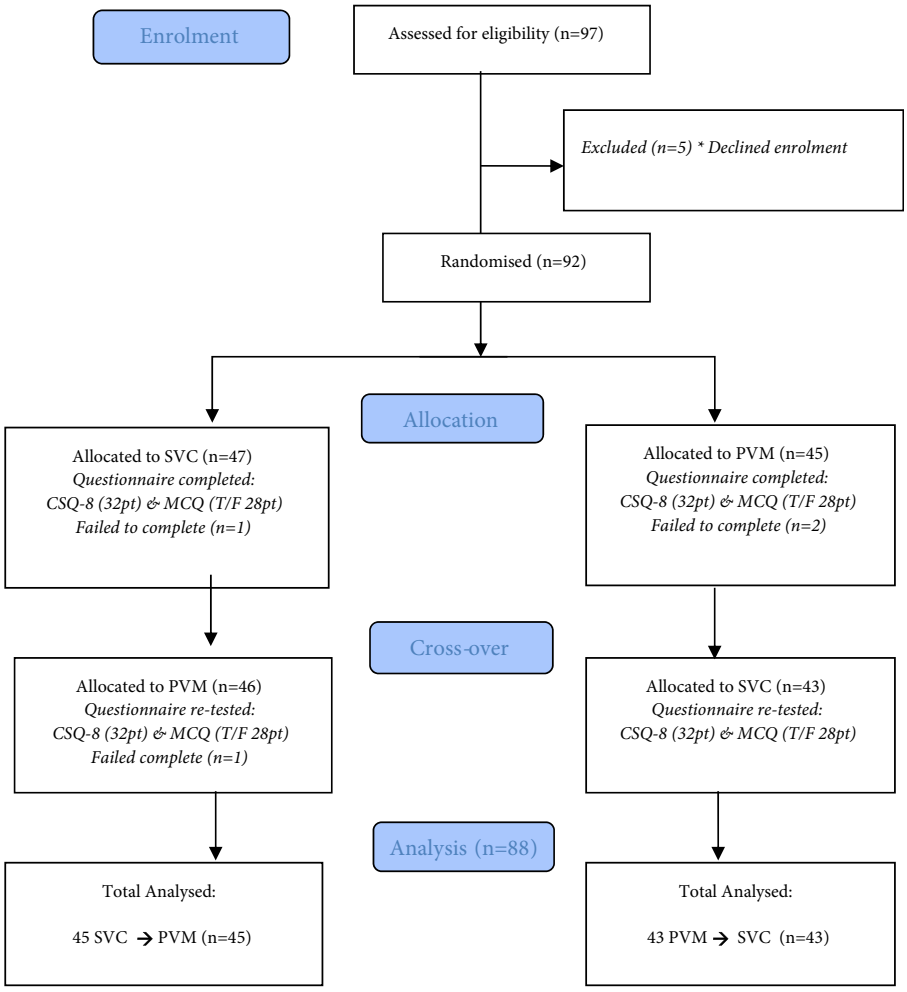


Table 1 Baseline characteristics.

Variable	SVC as first intervention	PVM as first intervention
Mean age, years	43	45
%:		
Male sex	76	74
English first language	93	79
Educational level secondary or above	73	74
Previous ureteric stent	31	26
Number of hospital visits for renal stones	2	1.4

SVC, standard verbal communication; PVM, portable video media.

Discussion

Informed consent has traditionally been acquired through a verbal process with or without some written documentation of this process occurring [3]. Studies have shown that recall of information in the context of verbal informed consent is often inconsistent and poor, with recall of information on the same day as the informed consent process varying between 18% and 81% [18]. Educational aids such as pamphlets and brochures have been shown to improve patient satisfaction with the informed-consent process [19]. Education and health literacy form a barrier for these aids being useful to patients [16].

Previous studies have shown that increased patient comprehension and retention has been associated with improved clinical outcomes [20]. Empowering patients with knowledge is a central tenet of clinical excellence resulting in improved clinical outcomes and patient compliance, while minimising complication rates and litigation [1,8,12,21,22]. Current evidence shows that some patients undergo procedures without true informed consent being achieved. The process is either inconsistent or variably comprehended by patients from different educational and language backgrounds [23]. Currently, SVC is a highly variable process depending on time availability, clinician training, technical skills, and patient background. Content is often delivered in

Fig. 2 Knowledge and satisfaction scores after each intervention. *$P < 0.001$.

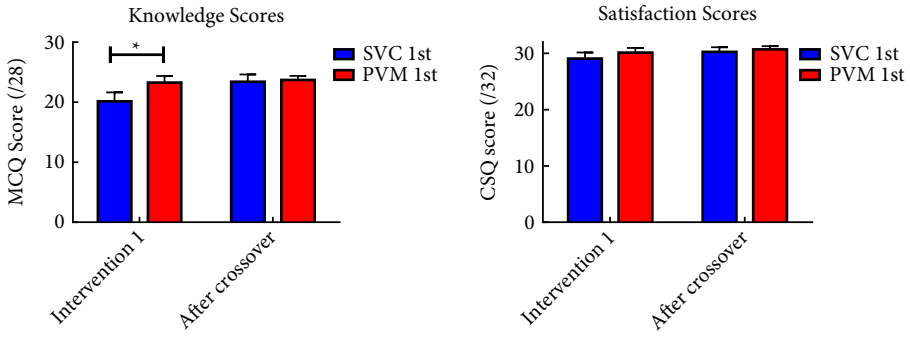


Table 2 CSQ-8 and multiple choice question (MCQ) scores after first intervention and crossover to the other intervention.

	SVC as first intervention, mean score (95% CI)	PVM as first intervention, mean score (95% CI)
After first intervention		
MCQ*	20.13 (18.64–21.63)	23.26 (22.16–24.35)
CSQ-8	29.07 (27.96–30.17)	30.16 (29.36–30.97)
After crossover		
MCQ	23.71 (22.98–24.45)	23.42 (22.22–24.62)
CSQ-8	30.27 (29.43–31.10)	30.72 (30.16–31.28)

*SVC, standard verbal communication; PVM, portable video media. *$P < 0.05$.*

either a busy outpatient clinic or emergency setting, which is often pressured by time, noise, and distractions.

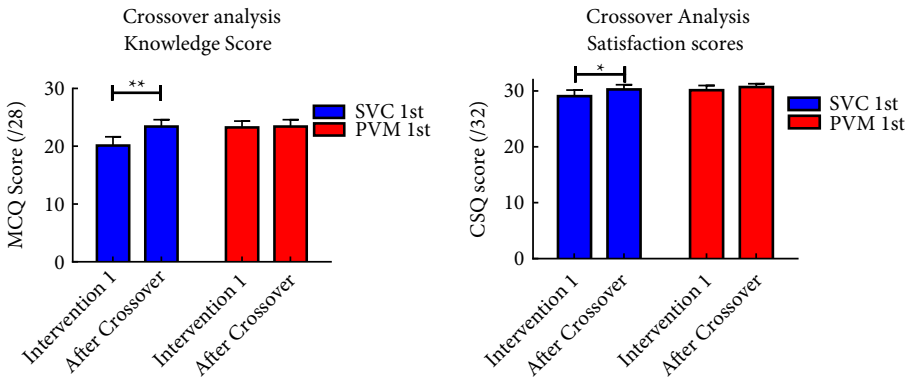
Video-based education shows promising early results with the advent and ubiquitousness of portable, hand-held, mobile media devices. The portability of these small devices lends itself for easy use within a busy hospital environment. PVM offers the benefit of reproducibility, availability, and repeatability. The design of any potential informed-consent videos needs to acknowledge the intended population and healthcare setting, whilst remaining culturally and socially appropriate to patients. This has been shown to make such videos more effective to target populations [24].

The results of our present study show that PVM leads to increased patient understanding and information retention compared with SVC. PVM leads to a significant 15.5% increase in knowledge scores at initial intervention and a significant 17.9% increase in knowledge score after patients receiving SVC were crossed over to the PVM arm.

Whilst patient satisfaction was measured as the same between both groups, there was an overwhelming patient preference towards PVM in the urological consent process (80.7% vs 19.3%). Whilst not formally explored in our present study, anecdotal feedback from the 17 patients (19.3%) that preferred SVC were concerned about the lack of clinician input and ability to ask questions. The results of our present study suggest that PVM is a useful adjunct to the current consent process.

The limitations of the present study lie in the inability to truly blind the intervention order to the Doctor performing the SVC and the presence of the Hawthorne effect. This may have contributed to a more meticulous SVC compared with normal practice. Another limitation of the study was the difficulty in restricting patients from pausing and rewinding the PVM presentation in order to reinforce specific details. This may have led to improved patient knowledge acquisition. A further limitation of the present study was the

Fig. 3 Knowledge and satisfaction scores within group after crossover. **$P < 0.001$, *$P = 0.006$.



paucity of validated questionnaires in assessing patient understanding specifically for cystoscopy and ureteric stent insertion. A targeted true/false questionnaire (MCQ) created by the authors was used. Analysis of knowledge recall using this method, which has not been previously validated opens the data to potential bias. A limitation of our present study is whether PVM would be useful for complex procedures with surgical and patient variability.

The multi-centre and randomised control aspect of the present study has been designed to eliminate selection bias as well as improve external validity. The standardised nature of the cystoscopy and ureteric stent insertion lends itself to a study on video-assisted education. Our present results have the potential to be extrapolated to other procedures that have a standard technical process.

In conclusion, we propose that PVM is an extremely useful adjunct for improving informed consent. PVM has the possibility for wider applicability to other surgical procedures and the broader medical community for patient education. Further studies are required to assess the applicability of PVM for such uses, particularly in the setting of complex procedures, to confirm our present findings.

Author Contributions

Winter M: conception and design of the study, acquisition, analysis and interpretation of data for the work, drafting of manuscript. Kam J: acquisition, analysis and interpretation of data for the work, drafting of manuscript. Nalavenkata S: acquisition, analysis and interpretation of data for the work, drafting of manuscript. Hardy E: conception and design of the study, acquisition, analysis and interpretation of data for the work. Handmer M: conception and design of the study, acquisition, analysis and interpretation of data for the work. Ainsworth H: acquisition, analysis and interpretation of data for the work. Lee W: conception and design of the study and interpretation of data for the work. Louie-Johnsun M: conception and design of the study, interpretation of data for the work, supervision of study. All authors were involved in drafting the work or revising it critically for important intellectual content and have approved the final version to be published. All authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Central Coast Urology Research and Education Fund.
Registration: This trial is registered with the Australian New Zealand Clinical Trials Registry (ANZCTR) ACTRN12614000687695.

Institutional Approval

This trial was approved by the ethics committee of Northern Sydney Local Health District and the Institutional Review Board of Central Coast Local Health District.

Conflicts of Interest

The Central Coast Urology Research & Education Fund provided financial support to conduct this study. Dr Matthew Winter is a consultant for Specialist Productions, a video production company which specializes in the development of audio visual presentations aimed to assist in patient education.

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Abbreviations: CSQ-8, client satisfaction questionnaire 8; MCQ, multiple choice questions; PVM, portable video media; SVC, standard verbal consent.

Supporting Information

Additional Supporting Information may be found in the online version of this article:

Video S1. Edited video used in the portable video media (PVM) arm of this trial.