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Improving informed consent for patients undergoing radical prostatectomy using multimedia techniques: a prospective randomized crossover study

Dennis Gyomber, Nathan Lawrentschuk, Peter Wong, Frank Parker and Damien M. Bolton

University of Melbourne, Department of Urology, Austin Health, Heidelberg, Australia

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OBJECTIVE

To compare the comprehension gained by standard consent (SC) vs a unique interactive multimedia presentation (IMP), for radical prostatectomy (RP), as informed consent for RP requires that the patient understands the procedure and potential complications.

PATIENTS AND METHODS

Forty patients undergoing RP were prospectively randomized to SC or IMP, followed by a 26-question test on critical aspects of the surgery and its implications. The groups were crossed over and re-tested, with a subsequent statistical analysis. SC involved typical verbal interaction and consultation with physicians and nurses, whilst the IMP provided consistent and animated information on these topics, and included multiple-choice questions probing understanding of key points. Progression through the IMP only occurred with correct responses; incorrect responses prompted a review of the information before repeating the question. Telephone interviews assessed usability, overall understanding, educational level and primary language.

RESULTS

The patient groups had similar demographics. The IMP group (78%) had significantly higher knowledge test scores ($P < 0.001$) than the SC group (57%), suggesting a better understanding of the implications of surgery. This was maintained on crossover, with the SC group scores improving by 11% compared to testing before IMP ($P < 0.001$). The initial IMP group scores were unchanged on crossover and repeat testing ($P < 0.05$).

CONCLUSION

IMP provides better patient understanding than SC for RP, by ensuring that the procedure and risks have been explained consistently, and by actively testing the patient. Such tools assist in obtaining ethical and legally informed consent, thus increasing patient knowledge whilst reducing patient anxiety and potential dissatisfaction or medico-legal consequences when less than ideal outcomes occur.

KEYWORDS

prostate neoplasm, prostatectomy, informed consent, multimedia, patient education handout, computer-assisted decision making

INTRODUCTION

The essence of informed consent for a surgical procedure implies a duty of care by the surgeon to convey general and specific information, so that the patient has sufficient understanding of the procedure and potential risks as they relate to that individual [1]. Aside from these ethical obligations, legal obligations also mould the consent process [2]. The procedure of radical prostatectomy (RP) can be associated with significant morbidity and at times even mortality [3–7]. The procedure itself, alternatives, potential oncological outcomes, and complications such as erectile dysfunction and incontinence, need to be understood by any patient contemplating such surgery. Finally, there should be an opportunity for patients to revisit the risks and benefits after the initial urological consultation [8].

Traditional standard consent (SC) involves a verbal interaction between the patient and doctor, which often consists of the doctor describing the procedure and listing all of the potential complications. This didactic approach fails to ensure that patients have understood the information [9,10], and therefore is probably inadequate for true informed consent [11]. The first step in obtaining informed consent is to facilitate patient understanding of the procedure and associated risks. Aids to improve patient understanding have included written information (pamphlets), illustrations, educational videos and computer programs, and are in general considered a positive initiative as they are knowledge-building materials [12]. However, in a randomized trial for transurethral surgery, additional written consent did not improve patients' understanding of the nature of the surgery or the risks and complications of the procedure [13].

Hence currently available patient education materials and aids in the area of early-stage

prostate cancer treatment might contain comprehensive information about the risks and benefits of each treatment, but usually then simply assume patient understanding rather than documenting such insight. Previous authors concluded that a new generation of materials is needed for this purpose, to assist patients and surgeons in providing objectively informed consent on treatment options and outcomes [14]. Recently in a randomized trial, Internet-based patient-support information was used to inform patients about prostate cancer screening [15]. Despite the availability of multimedia resources there is a paucity of data on their capabilities and usefulness as part of the consent process.

This aim of the present study was to show that not only does a simple interactive multimedia presentation (IMP) improve patient understanding compared to SC for RP, but also that the IMP improves the understanding of patients already exposed to the traditional SC.

PATIENTS AND METHODS

Forty consecutive patients on the waiting list for open RP were randomised by computer, using sealed envelopes, to the SC process or consent via an IMP. Patients had to speak and read English, but not necessarily as a first language. Patients having a second opinion were excluded, as their knowledge base was considered biased. All patients were consented to participate in the trial, with institutional privacy and ethics guidelines followed.

For SC, patients agreed to have surgery after discussing all options, and once they had decided on surgery were given the standard booklet from our hospital on the surgery, complications and what to expect. This gave patients time to learn and understand the procedure, and have formulated questions. Thus at a separate visit 3 weeks after agreeing to have surgery, SC was obtained, which involved the traditional verbal interaction between the patient and a doctor, as well as the nurse at a pre-admission clinic, reflecting current consent practices at our institution. The surgical procedure and hospitalization were explained and possible complications addressed (continence, blood loss, erectile dysfunction, infection, anaesthesia, etc.) [16–19], as previously described [2]. A pamphlet outlining the same information was again given to all patients. The nurse and doctor (urology residents) providing consent worked from a checklist of issues to cover regarding the surgery and potential complications, and were unaware as to who was on the trial, so as not to provide additional or less information. As our institution is a university teaching institution, all patients were informed that the procedure would at least in part be performed by a trainee under supervision [20].

The content of the IMP was first developed based on information provided in our SC [2,16–19] but using graphics to explain anatomy and the surgery, resulting in 60 slides (PowerPoint 2003, Microsoft Corp., USA). Comments were then solicited on its content from 10 urologists and four nurses, as well as five patients, to modify the content. The final version contained 51 slides. Test-re-test reliability of the survey was assessed on five volunteers, 10–14 days apart, giving correlations of 0.85–0.97. The English language in the presentation was assessed as equivalent to seventh grade level (Flesch-Kincaid Reading Level) by software analysis (Microsoft MS Word 2003).

Of the 51 slides in the IMP, two are for the introduction and conclusion; five more cover basic genitourinary anatomy and function of the prostate; 13 outline the aims of the operation, anaesthetic and the basic steps, with animations (Fig. 1). Eight slides are for complications, and one for postoperative information. The remaining 22 slides contain embedded interactive questions related to the animations and information provided (Fig. 2). Patients can only progress to the next slide when the correct response is chosen. An incorrect response results in reviewing the relevant information and then being asked the question again. The patient can review the information an unlimited number of times.

The 51 slides were on a software platform easily operated on all personal computers in the hospital. The patient had a short demonstration on how to navigate the IMP, by clicking the left button of a mouse onto an appropriately labelled and coloured hyperlink. This requires minimal computer training and no significant computer skills. The IMP was administered either before SC or immediately after SC and completion of the initial knowledge test, depending on randomization.

Immediately after surgical consent for RP by SC or IMP, both groups then had their understanding of the procedure assessed by 26 multiple-choice questions testing understanding and complications of RP. The development of these questions followed the same process as that undertaken and described for the development of the IMP, with a literature review as well as peer, nurse and patient review before determining the final questions.

The format of these questions was 'true or false' and 'select the best response', and the questions had specifically not been presented as part of the IMP for those patients who had used this form of consent first. Questions on the complications of RP were derived from previous reports [16–19]. The patients were not given answers after testing. The two groups then crossed, so that those in the initial SC group undertook the IMP, and vice versa. Patients were then tested with the same test once again. A valid consent form was then signed before RP.

Finally all patients received a follow-up telephone call to grade aspects of the IMP; its ease of use, whether they were satisfied with information, and whether they would be happy to use the IMP for future consents. The primary language spoken and level of education was also recorded at that time.

For the statistical analysis we used the Mann–Whitney test to compare results between the groups, and the Wilcoxon signed-rank test used to compare results within groups on crossover. A box-plot analysis was also used. The study was powered to detect a 15% difference between groups, as this was felt to be clinically relevant.

RESULTS

Forty patients were randomised to the SC and IMP groups and all completed all components of the study. The mean age in the SC (first) group was 62 years and was 60 years for the IMP (first) group; 70% of patients (14/20) in both groups spoke English as a first language. The education level was also similar between groups; in the SC group six patients had completed primary school but had not completed secondary school, seven had completed high school, and seven had completed technical school, while in the IMP group five had completed primary school but had not completed secondary school, 10 completed high school, three completed

technical school, with two having tertiary education ($P < 0.05$). The mean time to complete the SC was 20 min, whilst the IMP took 18 min to complete. The knowledge test took a mean of 12 min to complete the first time, and 10 min the second time. The mean time to surgery after completing the consent was 3.5 weeks.

There was a significant difference ($P < 0.001$) in the test scores between the groups, with mean (and median) scores being 57 (64)% in the SC vs 78 (81)% in the IMP groups, respectively (Fig. 3). After crossover the SC group scores improved by 11% compared to before IMP testing ($P < 0.001$). The initial IMP group scores were unchanged on crossover and repeat testing. The IMP took 10 min longer to complete than the SC.

Most patients (67%) rated the IMP as easy or very easy to use. Of the 33% who found the IMP hard or very hard, 78% spoke English as a second language. Despite this, 82% were happy to use a similar interactive presentation for future surgical procedures.

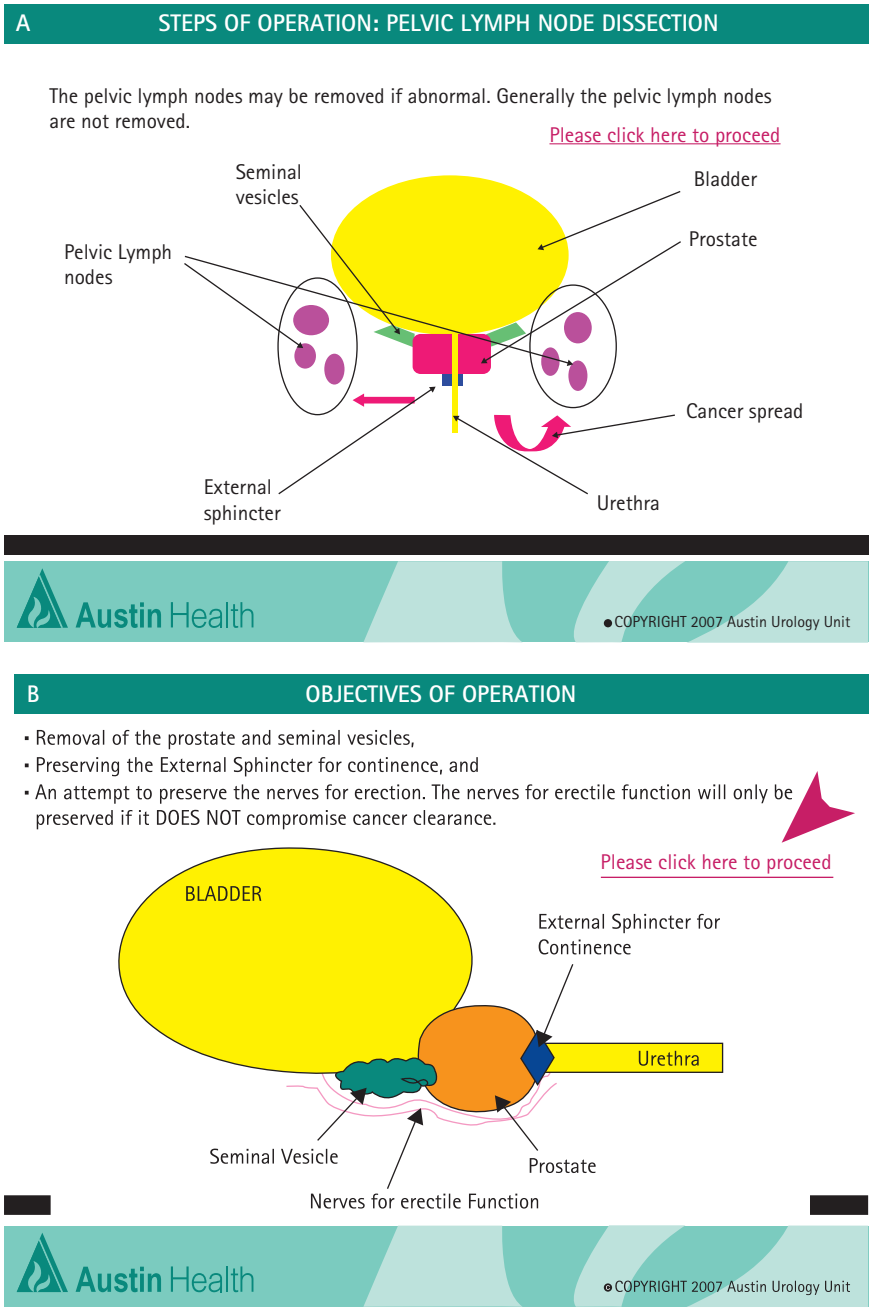
DISCUSSION

RP is a major procedure with potential for significant morbidity. Informed consent implies more than a doctor providing an explanation of the risks and benefits of a procedure to a patient; it involves the surgeon ensuring that sufficient information has been provided to enable the patient to understand the potential implications of such risks and benefits as they relate to the individual concerned.

For informed consent to be obtained the patient must have a functional understanding of the information provided. The IMP allows patient understanding to be ascertained using an objective assessment of consistent, interactive questioning. Successfully completing the IMP implies that the patient has an understanding of the key points of treatment, as progression through the consent process will only ensue with correct responses.

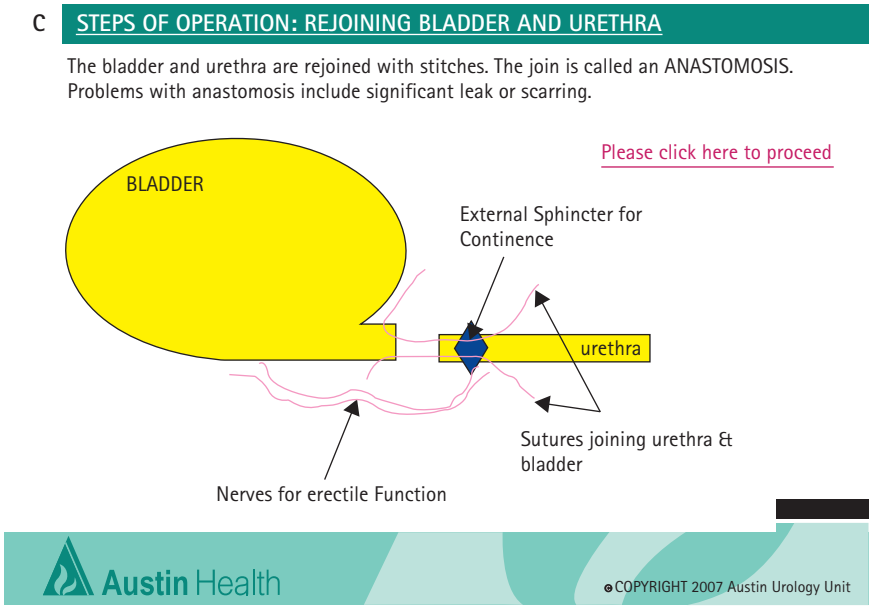
Consistent with the aims of this study, we showed that a simple IMP provides better patient understanding than SC for RP, as assessed on objective testing. It also appears that the IMP will improve the understanding of patients already exposed to the traditional SC. This study also explores the use of an often-overlooked tool in providing and assessing understanding of information for informed consent, by only allowing progression through the information when it is understood sufficiently to permit the correct answer to be given to a simple question on a key point about prostate cancer or RP.

FIG. 1. Three slides used outlining main objectives of open radical RP. The arrow indicates where the patient clicks to proceed (slide B).



Previous studies [16,21,22] found variable results in improving patients' understanding using various means of information delivery, but none have used a detailed multimedia presentation requiring patient interaction and feedback. Standardization of consent topics electronically in RP has also been useful [2], but again this ensures ethical and moral concerns are met for the coverage of topics,

FIG. 1. Continued



but not understanding by the patient. Also, no studies appear to have used crossover groups to assess if there can be an improvement in the control group or sustained understanding in the intervention group using this form of technology. The present positive findings strengthen the argument for using IMPs in helping to obtain informed consent.

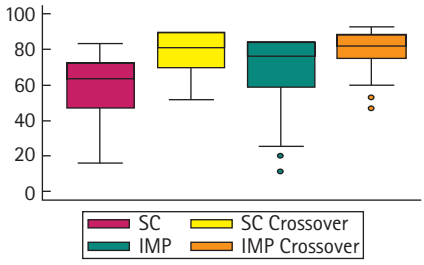
Although there are only limited data from the present and small studies using IMP for consent in an orthopaedic setting [23], the present patients appeared to be satisfied upon review with the IMP approach, and appeared to express a preference for this type of objective provision of information over verbal or written options. The IMP thus appears likely to enhance the surgeon-patient relationship by objectively ascertaining exposure to core information, and potentially freeing the surgeon to explore and focus on any more subtle issues that the patient might have identified as a consequence of conducting such an assessment. Completion of the IMP by a patient before surgery also ensures that the information has been delivered in a consistent and standardized manner, and provides documentation that all significant risks and complications have been presented to the patient. We continue to use the IMP at our institution because of the benefits to patients and staff involved with this procedure.

There is also scope for an IMP to record individual responses within the presentation that might help the surgeon to identify any core misunderstandings that require more in-depth explanation. For example, if the patient has not understood there is a significant chance of erectile dysfunction, due to repeatedly answering this question incorrectly, a medical practitioner can identify this and potentially spend more time addressing this issue. Such IMP data could be done remotely over the Internet or recorded in the office of the surgeon for later discussion and analysis.

To realise the full potential of the IMP there must be different language versions. Potential future improvements include voice recordings in different languages to eliminate the amount of reading, as well as creating animation clips which decrease the number of slides that patients would need to view. Furthermore, such interactive consent processes can be easily modified for minimally invasive RP and many other urological and surgical procedures. This is particularly relevant for robotic-assisted RP, where patients in one study were more likely to be regretful and dissatisfied, possibly because of higher expectation of an 'innovative' procedure [24], and the risks and benefits of new technologies during preoperative counselling might be assisted by an IMP.

FIG. 2. Slides explaining (A) then testing understanding of prostate function (B). If the incorrect answer is supplied the patient is returned to the information (C) and then asked to proceed to the question again. If the answer was correct they proceed to the next.

FIG. 3. Box-plot analysis of test scores before and after crossover. The x axis represents the percentage obtaining the correct answer. Line within box, median; Upper box border or upper hinge, 75th percentile; lower box border or lower hinge, 25th percentile.



Ultimately IMP might also be used for education of nurses, medical students and surgical trainees by permitting the presentation of a single collection of information at different levels of sophistication [25].

In conclusion, IMPs are a simple, cost-effective medium which appear to increase patient understanding of the risks and benefits of RP, when compared to SC procedures. Through increased patient understanding there can be more meaningful discussions about surgery, ultimately improving doctor-patient relationships and achieving truly informed consent. Most patients found the IMP easy to use and were satisfied with the information provided. The IMP has the potential to be enhanced with audio, video and multiple-language formats. Such tools assist in obtaining ethical and legally informed consent, thus increasing patient knowledge, whilst reducing patient anxiety and potential dissatisfaction or medico-legal consequences when less than ideal outcomes occur.

CONFLICT OF INTEREST

None declared.

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Correspondence: Nathan Lawrentschuk, University of Melbourne – Surgery and Urology, Austin Hospital 8th Floor, HSB Studley Road Heidelberg Victoria 3084, Australia.
e-mail: nayjay@ozemail.com.au, lawrentschuk@gmail.com

Abbreviations: **SC**, standard consent; **IMP**, interactive multimedia presentation; **RP**, radical prostatectomy.