

Multimedia Support for Improving Preoperative Patient Education: A Randomized Controlled Trial Using the Example of Radical Prostatectomy

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ABSTRACT

Background. Growing evidence supports the use of multimedia presentations for informing patients. Therefore, we supported preoperative education by adding a multimedia tool and examined the effects in a randomized controlled trial.

Methods. We randomized German-speaking patients scheduled for radical prostatectomy at our center to receive either a multimedia-supported (MME) or a standard education (SE). Outcomes were measured in a structured interview. Primary outcome was patient satisfaction. In addition, we applied validated instruments to determine

anxiety and measures of decision-making. Results were given by mean and standard deviation. For comparison of groups we used *t* test and chi-square test. For an explorative analysis we applied multivariate logistic regression.

Results. We randomized 203 patients to receive MME ($n = 102$) or SE ($n = 101$). Complete satisfaction with preoperative education was more frequent in the MME group (69 vs 52 %, $p = .016$) and patients after MME reported more questions (5.7 vs 4.2, $p = .018$). There was no difference concerning the duration of talks and the number of recalled risks. However, perceived knowledge was higher after MME (1.3 vs 1.6, $p = .037$). Anxiety and measures of decision-making were comparable. Patients judged the multimedia tool very positive, and 74 % of the MME group thought that their preoperative education had been superior to SE.

Conclusions. Multimedia support should be considered worthwhile for improving the informed consent process before surgery (www.germanctr.de; DRKS00000096).

Previous Presentations A portion of this work was presented in abstract form as a poster at the 63rd Annual meeting of the German Urological Association, September 14–17, 2011, Hamburg, Germany, and at the 31st Congress of the Société Internationale d’Urologie, October 16–20, 2011, Berlin, Germany. Moreover, our project won the “Best Practice Award 2012” (first prize). This scientific initiative from the German Cancer Society (DKG) in cooperation with the sponsor Novartis Pharma GmbH, Germany honors efforts to improve communication for cancer patients.

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As a standard of care and an ethical obligation, every invasive diagnostic or therapeutic intervention requires previous informed consent. Therefore, in clinical routine, patient education prior to an intervention is a very frequent task that is generally underestimated. However, it can be challenging to comprehensibly impart a basic understanding of the planned procedure, its implications, risks, and future consequences. This task might be eased by improved visualization, and consistently growing evidence supports the use of multimedia presentations for informing

patients.^{1–3} Especially in highly standardized situations such as preoperative education for routine surgery, patients might profit best from didactic improvements.⁴

Therefore, we supported preoperative patient education with a computer-based multimedia tool and examined the effects in a randomized controlled trial using the example of radical prostatectomy. Unlike the vast majority of comparable projects providing additional content detached from the physician-patient interaction, we directly involved the multimedia application into the preoperative talk.¹ The resulting setting was comparable to using presentation software: The physician navigated the multimedia tool to illustrate the preoperative talk with pictures, short videos, and some written information.

The aim of our study was to compare standard preoperative education (SE) and multimedia-supported education (MME) prior to radical prostatectomy. Based on our explorative pilot study we selected overall satisfaction with preoperative patient education the main outcome criterion.⁵ Moreover, we assumed that MME would result in increased patient satisfaction compared with SE.

METHODS

We follow the Consolidated Standards of Reporting Trials statement.⁶

Explorative Pilot Study

To decide on important aspects of the study design we conducted an explorative pilot study.⁵ In 30 consecutive patients we performed semistructured interviews focusing on their preoperative education. Thereby, we revised the interview manual and the applied instruments.⁵ To cover possible changes over time we asked for the patients' view the day before and 15 days after radical prostatectomy. As this pilot study did not render substantial differences, a single preoperative inquiry date seemed sufficient.⁵

Study Design

We chose a randomized controlled study design with parallel and equal allocation of groups. Because of the nature of the intervention, blinding was not possible. We conducted the study in the Department of Urology at the University Hospital of Heidelberg, and its Institutional Review Board approved the study protocol (Vote S-213/2007). We registered the study within the German Clinical Trials Register (www.germanctr.de; DRKS00000096), and no methodological changes had to be performed after trial commencement.

Participants

Eligible were German-speaking patients over 18 years of age who were scheduled to undergo radical prostatectomy with curative intent the following day. Consequently, limited capability of communicating in German and missing consent were exclusion criteria.

Randomization

Randomization occurred in blocks of 10 and equal proportions (5:5) to receive either SE or MME. Accordingly, JH created a random list, which was concealed from investigators. There were eight specialist trainees for urology who participated in the study.⁷ Within the routine admission procedure the day before radical prostatectomy, they assessed eligibility of patients and asked for oral and written informed consent. After inclusion, a study nurse referred to the random list and assigned the patient to the corresponding intervention.

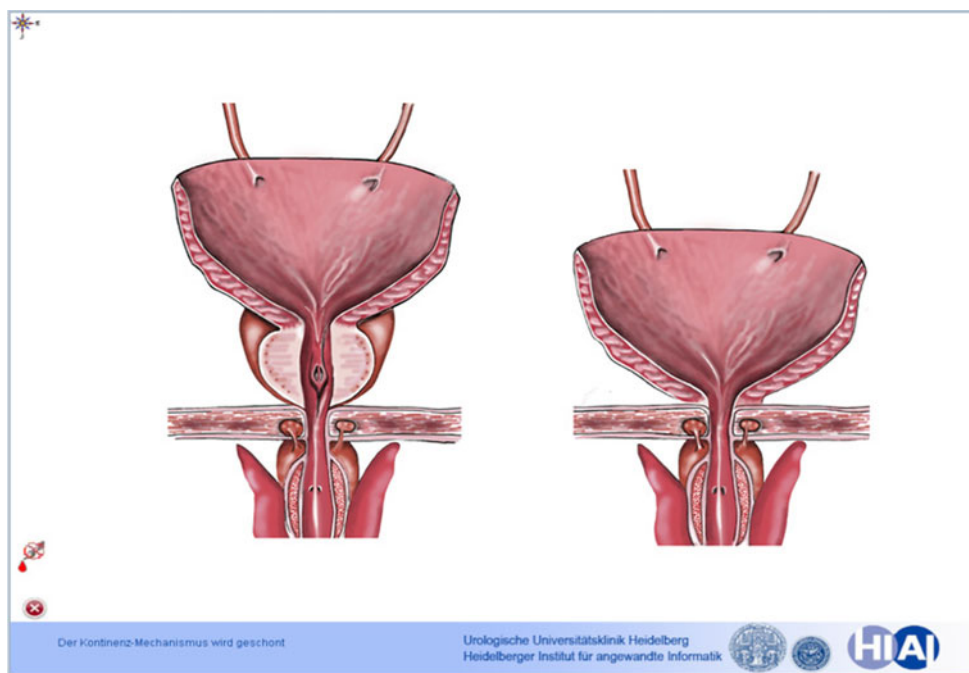
Intervention: Multimedia-Supported Education (MME) vs Standard Education (SE)

In both groups we provided our patients with a commercially available consent form (proCompliance GmbH, Erlangen, Germany) to read before the consultation. As in clinical routine we used this form to ease explanation during the talk for SE, whereas the multimedia tool took over this function for MME. Therefore, both groups received the same information by different modes of presentation. To ensure legal certainty we further used the established consent form for all patients to document informed consent in writing.

Our interdisciplinary group developed the multimedia program stepwise over 1 year. After setting up the concept and initial software development, the study group, three patients, and several lay people from different backgrounds conducted a structured evaluation. Then we improved the tool, did a similar retesting, and set up the final version (see supplemental digital content for an adapted English open-source version). It included several self-designed graphics (Fig. 1) and some content from Intuitive Surgical Inc. (Sunnyvale, CA) that we used with permission. The multimedia tool covered important aspects such as anatomy, the surgical procedure, side effects, and the general treatment course (supplemental digital content).

For software development we used Adobe Director 11 (Adobe Systems Inc., San Jose, CA) for Windows XP or higher (Microsoft Corp., Redmond, WA). According to the idea of user-centered design (ISO 13407), we shaped the multimedia tool (design EN ISO 9241 parts 110 and 12) by evolutionary prototyping.

FIG. 1 Screenshot of the multimedia tool used for MME (Media Centre, University Hospital Heidelberg)



Thereby, several features proved to be useful: A decent interactive interface allows the physician to navigate between illustrations, video sequences, pictures, and textual content. The video sequences can be repeatedly played, paused, or rewound. Moreover, there is an activatable tool for drawing diagrams in different colors to highlight information. Depending on the agreed surgical details (open retropubic vs robotic, nerve-sparing vs non-nerve-sparing) the physician can choose an adjusted preselection of slides at the very beginning. Alternatively, a general mode allows discussion of these surgical options. To freely move within the whole content, an always-accessible thumbnail view offers fast navigation. A log file automatically saves all actions conducted in the program.

Primary Outcome Measure and Determination of Sample Size

We considered patient satisfaction the most relevant outcome. Based on previous work we decided to use a pragmatic way to measure overall satisfaction on a 6-point Likert scale from “+++” to “---” with a single item: “Overall, I am satisfied with the preoperative education”.⁸

Within our pilot study we found a useful differentiator for our patients’ opinion: overall satisfaction concerning SE was rated maximal (+++) by 57 % and less positive by 43 % ($n = 30$).⁵ Therefore, we defined the rate of complete overall satisfaction the primary outcome measure and designed a confirmatory trial with respect to this dichotomous parameter. To detect a difference between two groups (SE vs MME) caused by an effect of moderate

size (0.3) the calculated sample size was 87 per group to provide 80 % power in a 2-tailed chi-square test with alpha set at 0.05. With an estimated dropout rate of 20 % we planned to randomize 220 patients total.

Secondary Outcome Measures

The treating physician objectively measured the consultation’s duration by using a stopwatch. We collected all other data in a structured interview on the inpatient ward within 6–10 h after the preoperative education. Interviews were identical in both groups, except for a few more questions specifically referring to the multimedia tool in the MME group. An experienced psycho-oncologist (AI) trained two research assistants (BK, NL) to conduct these interviews according to a detailed manual that we had carefully revised after piloting.⁵ Part of this standardization was to explain to every patient that his answers were anonymous to treating physicians.

We complemented sociodemographic statements with clinical data from patient records and assessed erectile function with the short form of the international index of erectile function (IIEF).⁹ To categorize education levels we defined “none or basic” as missing school-leaving qualification or uncompleted professional training. Having passed senior technical college or university characterized “higher education” with all remaining patients having “medium” educational level. Within the structured interview we asked for features of information needs and decision-making. As an indicator for perceived involvement, we asked the patients for their estimate on how many

questions they had posed. Moreover, we assessed knowledge of personal clinical data by asking for the latest prostate specific antigen (PSA) count, the biopsy's Gleason score, and the approximate prostate volume. We defined having a "high level of information" by correctly stating two of these three parameters.

Patients' actual gain of knowledge caused by preoperative education was not our primary focus. That was the reason we avoided designing our outcome measurement like a test and only assessed one objective criterion of gained knowledge: We asked for risks of surgery and determined the remembered quantity. However, we measured perceived knowledge as part of a self-designed questionnaire with the statement: "I feel well-informed about the planned procedure and possible risks by today's consultation." It also included the item on overall satisfaction and every single item was rated from "+++" to "---" on a 6-point Likert scale. For data analysis we coded this scale with 1 (++++) to 6 (---). The self-designed questionnaire aimed at various aspects of preoperative education and was carefully reassessed after piloting.⁵

Finally, we administered two validated questionnaires to determine anxiety and measures of decision-making: the state part of the state-trait anxiety inventory (STAI) makes up a sum score of 20–80 points with higher scores indicating a more intense state of anxiety.¹⁰ The combined outcome measure for risk communication and treatment decision-making effectiveness (COMRADE) comprises a 20-item questionnaire equally focusing on "risk communication" and "confidence in the decision".¹¹

There were no changes to trial outcomes after the commencement of the trial and data analysis was by intention to treat. Nevertheless, we performed an additional exploratory analysis.

Statistics

For data checking we selected a 10 % random sample and found satisfactory quality with an error rate of items <0.5 %. We presented categorical data by absolute and relative frequencies, continuous data by mean and standard deviation. For comparing the groups we used the chi-square test and *t* test. As a complementing sensitivity analysis for the primary outcome measure we also tested overall satisfaction according to its ordinal scale raw data and thereof computed the effect size. We calculated 95 % confidence intervals (95 % CI) for primary and secondary outcomes. Moreover, we performed an explorative analysis using multivariate logistic regression to identify predictors of complete satisfaction. All tests were two-tailed with

alpha set at 0.05. We performed all calculations with PASW Statistics 18.0 (Chicago, IL).

RESULTS

Recruitment and follow-up lasted from March 6, 2009 until July 27, 2010, when we accomplished the scheduled number of 220 randomized patients. During this period, 385 patients underwent radical prostatectomy at our institution, 246 of whom (64 %) we assessed for eligibility. Figure 2 depicts participant flow. We were able to analyze data sets from 203 patients who received MME ($n = 102$) or SE ($n = 101$). We performed all comparisons within these two originally assigned groups.

All physicians were able to use the software without any problems. There was no difference between the groups regarding sociodemographic, personal, and clinical data (Table 1). However, the percentage of accompanied patients differed with 50 % for the MME and 33 % for the SE group ($p = .01$).

Primary Outcome Measure

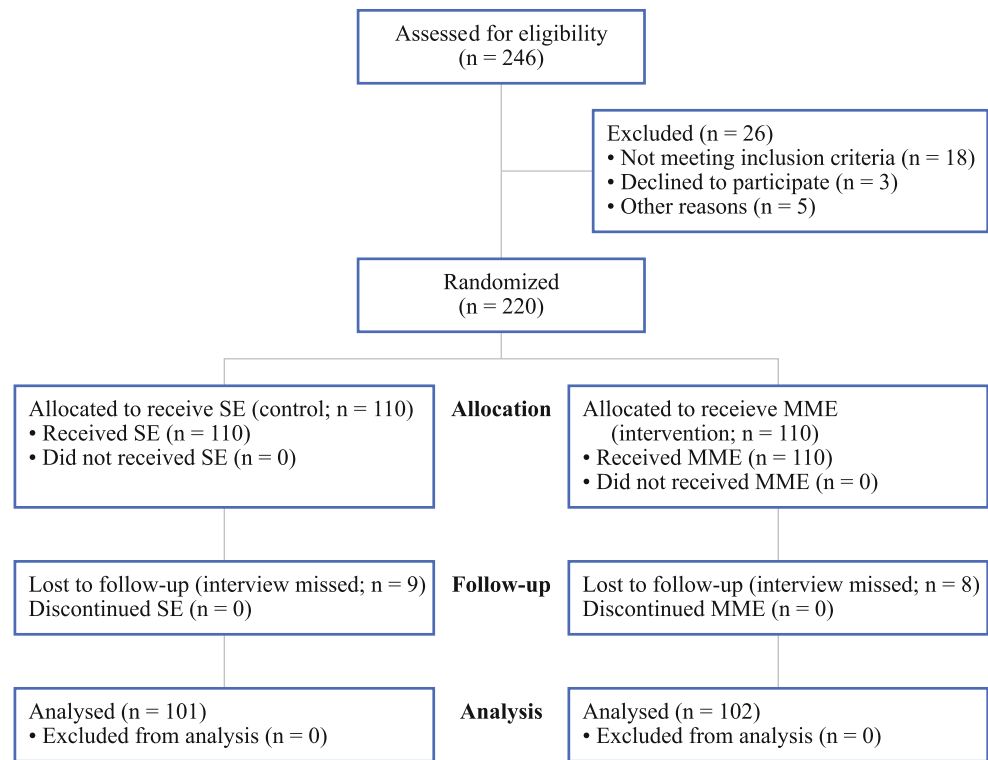
In the MME group 70 of 102 (69 %) patients reported complete satisfaction with preoperative education compared with 52 of 100 (52 %) in SE ($p = .016$). As a sensitivity analysis we also compared the raw data derived from a 6-point Likert scale and found a congruent result (Table 2). The calculated effect size of the intervention was 0.2.

Secondary Outcome Measures

There was no difference between MME and SE concerning their duration (Table 2). From both groups, 200 of 203 patients (98.5 %) stated that they had asked all questions they wanted to. Patients after MME reported more questions, 5.7 ± 5.4 compared with 4.2 ± 3.0 after SE ($p = .018$). The number of recalled risks was equal for both groups. However, perceived knowledge was higher after MME, 1.3 ± 0.6 compared with 1.6 ± 1.1 after SE ($p = .037$). The scores for anxiety, perception of risk communication, and confidence in the decision were equal (Table 2).

Ancillary Analysis

Within a multivariate model (Table 3) the intervention constitutes the strongest predictor of complete satisfaction concerning the preoperative consultation (odds ratio 2.7).

FIG. 2 Flow chart of eligible, randomized, and included patients**TABLE 1** Baseline demographic and clinical characteristics comparing both intervention (MME) and control group (SE)

Variable	MME (n = 102)	SE (n = 101)	p value
Age (years)	62.9 ± 7.3	63.8 ± 7.0	.35
Number of children	1.9 ± 1.0	1.8 ± 1.0	.30
Preoperative PSA (ug/l)	8.2 ± 5.3	10.2 ± 14.0	.18
Prostate volume (ml)	33.0 ± 15.5	36.9 ± 23.9	.16
Gleason score	6.5 ± 0.7	6.6 ± 0.8	.48
IIEF-5 score	18.7 ± 6.8	18.7 ± 7.0	.97
German native speaker	97 (95.1 %)	91 (90.1 %)	.17
Urban residency (>10,000 inhabitants)	81 (79.4 %)	81 (80.2 %)	.89
Education			.49
None or basic	11 (10.8 %)	7 (6.9 %)	
Medium	55 (53.9 %)	52 (51.5 %)	
Higher	36 (35.3 %)	42 (41.6 %)	
Privately insured	38 (37.3 %)	41 (40.6 %)	.63
Unmated	16 (15.7 %)	14 (13.9 %)	.71
Internet use for decision making	80 (78.4 %)	70 (69.3 %)	.14
Surgeon personally known	39 (38.2 %)	43 (42.6 %)	.49
High level of information	68 (66.7 %)	75 (74.3 %)	.24
Accompanied during preoperative education	51 (50 %)	33 (32.7 %)	.01

Additionally, also stronger confidence in the treatment decision and a higher number of questions asked impact positively on the patients' satisfaction.

TABLE 2 Comparison of outcomes for intervention (MME) and control group (SE)

Variable	MME (n = 102)	SE (n = 101)	p value	Difference (95 % CI)
Overall satisfaction	1.4 ± 0.6	1.6 ± 0.8	.024	0.2 (0.03–0.4)
Duration of preoperative education (min)	18.8 ± 5.0	18.9 ± 5.3	.89	−0.1 (−1.6–1.4)
Questions asked by patient	5.7 ± 5.4	4.2 ± 3.0	.018	1.5 (0.3–2.7)
Number of recalled risks	2.3 ± 1.2	2.4 ± 1.4	.90	0 (−0.4–0.3)
Perceived knowledge	1.3 ± 0.6	1.6 ± 1.1	.037	0.3 (0–0.5)
Anxiety (STAI (sum score))	42.6 ± 5.1	43.1 ± 4.9	.48	−0.5 (−1.9–0.9)
COMRADE risk communication (sum score)	43.7 ± 7.6	44.8 ± 6.0	.28	−1.1 (−3.0–0.9)
COMRADE confidence in the decision (sum score)	45.5 ± 5.7	45.8 ± 5.1	.68	−0.3 (−1.9–1.2)

Judgment of the Multimedia Tool by the Intervention Group (MME)

Patients judged the multimedia tool very positive: 98 of 101 (97 %) found the presentation clear and 95 of 101

TABLE 3 Multivariate logistic regression model to identify predictors of complete satisfaction

Variable	Odds ratio	95% CI	p value
Multimedia-supported education	2.7	(1.3–5.7)	.009
Anxiety (STAI) (sum score)	1.1	(1.0–1.1)	.08
COMRADE risk communication (sum score)	1.1	(1.0–1.2)	.05
COMRADE confidence in the decision (sum score)	1.2	(1.1–1.3)	<.001
Age (years)	1.0	(0.9–1.0)	.21
Internet use for decision making	0.5	(0.2–1.2)	.11
High level of information	0.7	(0.3–1.6)	.38
Accompanied during preoperative education	0.9	(0.5–1.9)	.85
Questions asked by patient	1.1	(1.0–1.3)	.018
Number of recalled risks	0.9	(0.7–1.2)	.39

(94 %) of adequate length. Of the 101 patients in the intervention group, 37 (37 %) appreciated the synchronous timing of the intervention. However, half of the patients would have preferred to also view the multimedia tool earlier: 45 of 101 (45 %) online at home and 5 of 101 (5 %) at the day of admission, but before the consultation. For 14 of 101 (14 %) the timing did not matter. Summarizing, 75 of 101 (74 %) of the MME group thought that their preoperative education had been superior to SE, 5 of 101 (5 %) did not think so, and 21 of 101 (21 %) were unsure about this question.

Only 14 % (14 of 101) would have liked to view photos or videos of real surgery. By the presented illustrations one patient was distinctly and four were slightly frightened. However, 93 % (94 of 101) were not frightened and two were undetermined. In neither group were there any further harms or unintended effects.

DISCUSSION

Principal Findings

Multimedia support significantly improves patients' satisfaction with preoperative education for radical prostatectomy. Moreover, patients reported a higher number of asked questions. We did not measure a change in objective knowledge, but subjectively perceived knowledge was higher after MME. The intervention proved to be well applicable in clinical routine and did not prolong the procedure. Patients' appraisal of the multimedia tool was very positive and suggested additional online availability as a possible improvement.

Strengths and Weaknesses of the Study

This is the largest study on synchronous multimedia support for preoperative patient education. So far, virtually every comparable intervention was delivered before or after the talk, and only 1 study used the same approach in a rather small sample (Table 4).¹² There were also certain limitations. Above all, the single center design and the impossibility of blinding were sources of bias. Randomization was successful in controlling other potential bias. Only the rate of patients with escorting persons was not equally distributed; this factor, however, did not impact on overall satisfaction in our multivariate model. Principally, most measures of patients' satisfaction show a ceiling effect that might overlay existing differences. While our primary outcome measure was not affected, this aspect also holds true for the COMRADE scale.¹¹ Moreover, our study was not powered to demonstrate effects in secondary outcome measures.

Mainly two aspects limited generalizability: The example of radical prostatectomy does not cover female patients, but relevant gender differences are only found infrequently.^{13–15} Moreover, we excluded patients with insufficient German language skills. However, the latter restrictions to generalizability are not a principal obstacle to the applicability of our findings, as two systematic reviews found no consistent differences for sex or minority status.^{1,16}

Comparison with Other Studies

We evaluated seven systematic reviews on computer-based interventions for patient education, but were not able to draw a conclusive picture thereof regarding the preoperative setting.^{1,2,16–20} Two of these reviews explored informed consent consultations, but focused exclusively on the research domain: Flory and Emanuel found better understanding in 3 of 12 studies, in which satisfaction was not improved, and anxiety was not assessed.^{2,16} A Cochrane review showed inconsistent findings when comparing four trials.²

To judge on the clinical field, we identified ten randomized controlled trials evaluating multimedia tools for improving informed consent before invasive procedures (Table 4). However, only one of the studies applied the same synchronous approach of integrating the multimedia application into the consultation.¹² Knowledge gain was the most widely assessed outcome (9 of 10 trials), and all of these trials consistently reported a significant improvement in this domain. In our study, we did not find an improvement in objective knowledge. However, we only used reminiscence of risks as a single surrogate parameter and did not put emphasis on testing our patients'

TABLE 4 Randomized controlled trials on multimedia support in patient education before an invasive procedure

Source	Scheduled procedure	Total sample size	Intervention compared with the standard informed consent procedure	Point of implementation in relation to the informed consent procedure	Significant changes in outcome		
					Satisfaction	Knowledge	Anxiety
Luck et al. ¹⁴	Colonoscopy	150	Supplemental information leaflet and video	1 week before	n.a.	R	F
Shaw et al. ²³	Colonoscopy	86	Supplemental interactive multimedia software	3–7 days before	R	R	=
Hermann ²⁴	Thyroidectomy	80	Supplemental video showing a 3D computer animation	Immediately before	n.a.	R	F
Enzenhofer et al. ¹²	Cardiologic or gastroenterologic interventions	56	Supplemental computer presentation	Synchronous	R	R	n. a.
Bytzer and Lindeberg ¹⁵	Colonoscopy	162	Supplemental information video	Directly after	n.a.	n.a.	=
Cowan et al. ²⁵	Intravenous contrast for computerized tomography	107	Supplemental information video	Directly after	R	R	n. a.
Bollschweiler et al. ¹³	Cholecystectomy	76	Supplemental interactive multimedia software	Asynchronous on the same day	=	R	=
Wilhelm et al. ²⁶	Cholecystectomy	212	Supplemental interactive DVD	Asynchronous on the same day	=	R	n. a.
Gyomber et al. ⁴	Radical prostatectomy	40	Supplemental interactive multimedia software (cross-over-design)	Asynchronous on the same day	n.a.	R	n. a.
Cornoiu et al. ²⁷	Knee arthroscopy	61	Supplemental multimedia education module (compared with verbal only education or written pamphlet)	Asynchronous on the same day	R	R	=

R risen, *F* fallen, = unchanged, *n.a.* not assessed

knowledge. Therefore, our study's contribution to this aspect is limited. At least, patients subjectively reported higher levels of perceived knowledge after MME. Also, six trials measured satisfaction and two-thirds (4 of 6 trials) found higher levels in the intervention group; the remaining third reported no difference. The evidence concerning anxiety was vice versa: Two-thirds (4 of 6 trials) found no effect, and one-third (2 of 6 trials) showed a reduction of anxiety levels. Therefore, our study results are consistent with existing evidence.

Improvements and Future Work

A modification requested by half of the patients should consist in providing the tool earlier for personal preparation. As an additional online feature or a multimedia DVD viewed before admission to the hospital, this information might even reduce stress by minimizing the unknown.²¹ However, our tool would need some adaption to this setting at least by establishing an audio commentary and some extra guidance.

Clinical and Research Implications of the Work

Based on the principle of patients' autonomy, reaching a true informed consent is an ethical ideal that should always be intended. Although its execution will not be perfect in clinical routine most of the time, all efforts have to be taken to comply with these high requirements. Therefore, it is ethically demanded to take advantage from additional assistance such as multimedia support.

After completing the study we conducted interviews with the eight physicians involved. All of them rated MME better than SE.⁷ Main reasons were better comprehensibility, the more memorable visual presentation, and greater ease in explaining complex issues. Given the choice, all eight physicians would use MME rather than SE.⁷ Therefore, both patients and physicians liked the multimedia tool better, it was easily integrated into clinical routine, and there were no harms. Moreover, the intervention is basically very simple and could be created with widely known presentation software. A more sophisticated solution could include documentation of informed consent.²² This would render paper-based forms unnecessary and save costs in the long run.

Radical prostatectomy is a good example for a highly standardized and frequently performed procedure. Our findings and evidence from the literature make us strongly believe that patient education for many different standard interventions would profit a lot by applying MME. An open-access model would be ideal for collecting useful multimedia material and providing it to the public. Moreover, an intelligent analysis tool could collect data from

routine use and help to further adjust the content according to its priority.

In conclusion, multimedia support should be considered worthwhile to improve the informed consent process before surgery-especially if the procedure is frequent, standardized, and possibly involves serious consequences.

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COMPETING INTEREST All authors declare: "I certify that all my affiliations with or financial involvement (e.g., employment; consultancies; honoraria; speakers bureau; stock ownership or options; expert testimony; grants; patents filed, received, pending, or in preparation; royalties; or donation of medical equipment) with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript are completely disclosed."

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