



Can teleconsent improve patient recall of surgical risks in knee arthroplasty? A randomised controlled trial

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Received: 13 June 2022 / Accepted: 7 September 2022
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Abstract

Objectives Informed consent plays a vital role in managing patients undergoing knee arthroplasty (KA). Unfortunately, patient recall of informed consent remains poor. Evidence has suggested that telemedicine and teleconsent can be safe, cost-effective, and well-received by patients. The primary aim of this study was to evaluate the effect of an additional preoperative teleconsent session on patient recall of surgical risks 1 month after knee arthroplasty. The secondary aim was to assess its impact on patient satisfaction.

Methods Sixty adult patients awaiting knee arthroplasty were randomly allocated to receive an additional preoperative teleconsent consultation (intervention group) or not (control group), along with the standard informed consent on the day of surgery. Participants were contacted 1 month after surgery to assess recall of surgical risks and satisfaction with the process. Demographics and education levels were recorded for each patient.

Results The mean recall rates were 16% and 12% in the study and control groups, respectively, with no significant difference ($p=0.42$). There was a significant difference between the mean satisfaction scores in the intervention group and the control group (9.8/10 vs 9/10, $p=0.0004$). Lastly, there was a significant positive correlation between the education level and the number of risks recalled in the study ($p=0.05$) and control groups ($p=0.04$).

Conclusion The additional preoperative teleconsent session had no significant effect on the risk recall rate but improved patient satisfaction. Our findings suggest education level may play a role in information recall. We can advocate for the increased use of teleconsent and telemedicine in patients undergoing KA or any elective orthopaedic procedure due to its perceived positive effects on patient satisfaction rates.

Keywords Informed consent · Knee arthroplasty · Memory · Patient satisfaction · Telemedicine

Introduction

Informed consent (IC) plays an integral role in the management of patients undergoing knee arthroplasty (KA). IC is obtained during a discussion between a suitably qualified clinician and their patient. A satisfactory result of such a discussion would be that the patient agrees or refuses the proposed treatment while possessing a sufficient understanding of its methods, risks and benefits, and the likelihood of occurrence. Patients should also be made aware of any alternative treatment options and make their final choice without coercion [1]. Discrepancies between patient and surgeon expectations

after surgery can lead to higher rates of patient dissatisfaction and, in some cases, litigation [1–3]. There has been renewed debate among medical professionals regarding strategies to improve IC protocols since the Montgomery vs Lanarkshire case was published in 2015 [4, 5]. This case exposed the shortcomings of modern healthcare systems when dealing with complex biopsychosocial factors surrounding IC in challenging situations. [4, 5] Another challenge facing clinicians is that patient recall of IC discussions is generally poor and decreases over time after the treatment intervention. [6, 7] In many healthcare settings, the IC process involves a preliminary informal discussion with the patient in the outpatient setting, followed by the formal consent discussion on the day of surgery. This practice is criticised for several reasons, including inadequate real-world resource availability to facilitate effective communication, time constraints putting pressure on patients and clinicians, and the inevitable utilisation

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of junior doctors to obtain consent for complex procedures. Suggestions including remote consultation have been made to expand resources to help tackle these challenges in the future. [8–11] The introduction of telemedicine and teleconsent in healthcare and healthcare-related research has provided exciting opportunities to expand services to many patients who previously might not have had easy access to these services. Furthermore, evidence has suggested that telemedicine and teleconsent can be safe, cost-effective, and well received by clinicians and patients. [9–11]

There is paucity in the literature regarding the use of teleconsent to increase the retention of information and understanding of surgical risk in patients undergoing KA. We hypothesised that an additional preoperative information session, in conjunction with the standard IC discussion on the day of surgery, should improve patient recall of surgical risks in patients undergoing KA. This is in comparison with patients who underwent IC on the day of surgery without the additional teleconsent session. The primary aim of this study was to evaluate the effect of an additional preoperative information session on patient recall of surgical risks 1 month after knee arthroplasty. The secondary aim was to assess its impact on patient satisfaction with the consent process.

Materials and methods

Ethical approval was obtained from our institutional review board before the start of the study. Sixty patients scheduled for primary KA were invited to participate in the study, and all agreed to take part. All participants provided informed consent to participate in the trial. This prospective parallel randomised controlled trial was conducted in an elective orthopaedic institution from March to June 2021. Participants were randomly allocated to an intervention or control group using Microsoft Excel (2021). Simple randomisation

was used, thirty participants were placed in each group and allocation was not blinded. The trial inclusion criteria were persons 18 years or older awaiting primary KA with the legal capacity to provide consent. Participants were excluded if they were illiterate, had any cognitive impairment, were awaiting revision surgery or needed an interpreter. All participants took part in a preliminary discussion with their treating surgeon about the risks and benefits of KA in the outpatient clinic. Consent forms are not routinely completed in the outpatient clinics in our institution due to the long average waiting times before surgery. Participants in the intervention group were contacted via telephone 1 week before their scheduled surgery. During this consultation, the *British Orthopaedic Association* (BOA) guideline for consent for knee replacement surgery was used to discuss all indications, risks and benefits of KA, and preliminary verbal informed consent was obtained for the surgery to go ahead [12]. Evidence has shown that patients struggle to retain information within the first week of receiving it [13]. This prompted the use of the 1-week time frame in this study between information sessions in the intervention group. Finally, all participants (intervention and control groups) were formally consented on the day of their surgery using this same BOA guideline, and consent was documented using the standard institutional consent form [12].

Patient demographic data were collected, including age, sex, previous contralateral KA, previous total hip arthroplasty (THA), and educational level. Patient education level was classified according to the *International Standard Classification of Education* (ISCED) [14]. The ISCED further divides all education levels into three broad categories: low education (levels 0–2), medium education (levels 3–4) and high education (levels 5–8). All participants were contacted via telephone 1 month after surgery and asked to list any risks they could recall. The 1-month time frame was chosen as this would be the halfway point between the 2-week

Table 1 Baseline characteristics of the groups

Demographic variable	Overall (<i>n</i> = 60) (SD or %)	Intervention group (<i>n</i> = 30) (SD or %)	Control group (<i>n</i> = 30) (SD or %)	Statistical significance
Age	63.7 (SD 9.2)	65.8 (SD 9.6)	61.5 (SD 8.5)	<i>p</i> = 0.07
Days after surgery	32.8 (2)	33.1 (2.5)	32.6 (1.4)	<i>p</i> = 0.55
Gender (M/F)	25/35 (42%/58%)	10/20 (33%/67%)	15/15 (50%/50%)	<i>p</i> = 0.19
Previous TKR	14 (23%)	8 (27%)	6 (20%)	<i>p</i> = 0.54
Previous THR	3 (5%)	3 (10%)	0 (0)	<i>p</i> = 0.08
ISCED Category ¹⁴				<i>p</i> = 0.139
Low	34 (57%)	17 (56.7%)	17 (56.7%)	
Medium	11 (18%)	8 (27%)	3 (10%)	
High	15 (25%)	5 (17%)	10 (33%)	

Results presented as mean (SD or percentage)

SD standard deviation, *n* number, TKR Total Knee replacement, THR Total hip replacement, ISCED International Standard Classification of Education

Table 2 Risk recall results

Variable	Intervention group	Control group	<i>p</i> -value (difference)
Risk recall scores (out of 14)	2.1 (1.8)	1.5 (1.5)	0.42
Satisfaction scores (out of 10)	9.8 (0.4)	9 (1)	0.0004
No risk recalled	6/30	11/30	0.152

and 6-week follow-up visits in this institution. A score was attributed to each participant based on the number of risks they could recall out of the fourteen risks mentioned in the guideline [12]. This method of evaluation is well established in the literature as an indication of the quality of the consent process. [15, 16] Participants were then asked to provide a rating between 0 (completely unsatisfied) and 10 (completely satisfied), reflecting their experience with the consent process. If a participant was unavailable, they were contacted again the following day.

The *Shapiro–Wilk* test was used to assess the normality of the data in our study. The *Student T-test* was used in data with a normal distribution, and the *Kruskal–Wallis* and *Wilcoxon rank-sum tests* were used in data with non-normal distribution. The correlation between variables was assessed with the chi-square (χ^2) and Spearman's *R* tests. Fisher's exact test was used in small data sample sizes (< 5). The level of significance was set at 0.05 for all statistical analyses. The results are reported as means with standard deviation (SD).

Results

Sixty participants participated in the study between March 2021 and June 2021, with thirty participants in each group. All participants in the intervention group received the pre-operative additional telephonic information session. All sixty participants completed the postoperative follow-up telephone consultation, and their data were included in the statistical analysis. There was no statistically significant difference noted in the baseline characteristics between the intervention and control groups concerning age, days after surgery, gender, previous THR, previous KA, and ISCED [14] category. The baseline characteristics of the groups are depicted in Table 1.

The number of risks recalled was 2.1/14 (SD 1.8) in the intervention group and 1.5/14 (SD 1.5) in the control group with no significant difference between the groups (Table 2). There were 11/30 participants (36.7%) in the control group and 6/30 (20%) participants in the intervention group that could not recall a single risk, which also was not a statistically significant difference (Table 2). When grouped by ISCED category, the mean recall scores were 1.3, 2.5 and 2.6 for the low, medium and high education categories, respectively. This was statistically significant between the categories ($p=0.02$). A significant positive correlation was found between risk recall and the ISCED category for the whole cohort and the control and intervention groups separately (Table 3). Age, previous THR or contralateral KA, gender and days since surgery had no significant effect on risk recall scores (Tables 3 and 4).

The most common risks that were recalled in the whole cohort of participants were pain (21/60), infection (20/60) and deep vein thrombosis (DVT, 18/60). Figure 1 depicts the frequency of each risk recalled in the control and intervention groups.

The mean satisfaction score was 9.8/10 (SD 0.4) in the intervention group and 9/10 (SD 1) in the control group. This was a statistically significant difference (Table 2). Patient age, whether they had undergone previous THR or contralateral KA, gender and days since surgery had no significant effect on satisfaction scores. There was no significant correlation between satisfaction score and ISCED [14] category for the whole cohort or the study and control groups separately (Table 3). When grouped by ISCED Category, the mean satisfaction scores were 9.5, 9.5 and 9.1 for the low, medium and high education categories, respectively. This difference in satisfaction scores between categories was not statistically significant ($p=0.62$). One participant in each group was unsatisfied and stated that the process needed improvement. The intervention group participant said not

Table 3 Correlation between recall scores and variables

Variable	Intervention group recall	Control group recall	Overall recall	Intervention group satisfaction	Control group satisfaction	Overall satisfaction
Age	-0.2795 (0.13)	-0.2012 (0.29)	-0.2068 (0.11)	-0.1732 (0.36)	-0.2233 (0.24)	-0.0551 (0.68)
Days since surgery	0.1982 (0.29)	0.0352 (0.85)	0.1507 (0.25)	-0.0508 (0.79)	-0.1729 (0.36)	-0.0665 (0.61)
ISCED category	0.3595 (0.05)	0.3801 (0.04)	0.3612 (0.01)	-0.3063 (0.1)	-0.0594 (0.75)	-0.1177 (0.37)

Results presented as correlation (*p*-value)

Table 4 Recall scores differences for the whole cohort

Variable	Risk recall scores (out of 14)	Satisfaction scores (out of 10)
Gender (25 males/35 females)	Males = 1.6 Females = 2.1 (<i>p</i> = 0.40)	Males = 9.4 Females = 9.34 (<i>p</i> = 0.98)
Previous THR (yes = 3/no = 57)	Yes = 3.7 No = 1.8 (<i>p</i> = 0.21)	Yes = 9.33 No = 9.37 (<i>p</i> = 0.80)
Previous TKR (yes = 14/no = 46)	Yes = 2.5 No = 1.7 (<i>p</i> = 0.21)	Yes = 9.36 No = 9.37 (<i>p</i> = 0.74)

Results presented as means (*p*-value of difference)

enough layperson English was used and that too many medical terms were used in the explanation. The control group participant stated that the person who consented them provided too much information on the day of surgery, which only increased their anxiety about the procedure.

Discussion

A growing body of evidence highlights the inadequacies of health systems in dealing with the clinical, financial and legal challenges surrounding informed consent [15–22]. Various studies have found a lack of standardisation and documentation of IC and that significant restructuring and widespread changes are needed to rectify the issues with guidelines within national and international settings [23, 24]. The varying contextual elements and levels of understanding among patients have also prompted experts to propose alternative strategies to aid healthcare workers when obtaining IC from patients who are increasingly informed and opinionated

[15]. Concepts such as shared decision-making, the use of technology to aid understanding, creative adjustment of consent to suit specific socioeconomic circumstances and the involvement of family and friends are highlighted as potential aids. The arrival of the COVID-19 pandemic has placed an uncomfortable spotlight on the shortcomings of medical systems worldwide, and the challenges have been exacerbated by the limitations placed on patient-clinician interaction during periods of restricted social and professional interaction. In this context, the body of literature examining the efficacy and safety of telemedicine has steadily grown over the past few years. There are encouraging findings showing that telemedicine offers safe, cost-effective and provides quality care to patients while resulting in high satisfaction rates among clinicians and patients. [9–11, 24, 25]

Patient recall of surgical risks associated with KA was poor in this study, with mean risk recall rates of 16% and 12% in the study and control groups, respectively. The poor recall rates were irrespective of group allocation and a comprehensive consenting process for all participants. These findings are in keeping with previously published studies from our institution by Power et al. [26] and Pomeroy et al. [27]. Johnson et al. compared patient understanding and satisfaction of IC between the three groups that underwent a standardised IC process along with variations of other modalities, including paper handouts, educational videos and nurse education [18]. They found no statistical difference in understanding or satisfaction between these three groups and suggested that reinforcement methods may not be necessary. Although these findings contrast with some of the outcomes from our study, it is essential to note that the additional interventions primarily involved non-interactive interventions and a session with a nurse coordinator/educator. These services are invaluable in themselves, but it may prove challenging to compare them to an information session with a treating surgeon when evaluating patient understanding of IC. A recent systematic review by Glaser et al. reported encouraging findings regarding the use of novel digital interventions that employ interactive features to improve patient comprehension of IC [28]. They also noted that interventions that utilised components such as test/feedback and teach-back methods seem to be the most helpful [28]. The findings in our study suggest that educational attainment may also play a role in IC recall and understanding. This is in keeping with previous reports from various institutions. [26, 29–31] Considering these factors, it can be argued that additional preoperative evaluation of patient understanding of the informed consent process may be warranted in some settings to aid patient understanding of their chosen treatment and its intricacies. This might enable institutions to have an “early-warning system” for patients who may not fully grasp the complexity of their treatment and allow extra time to further educate them regarding their options before deciding on a final course of action.

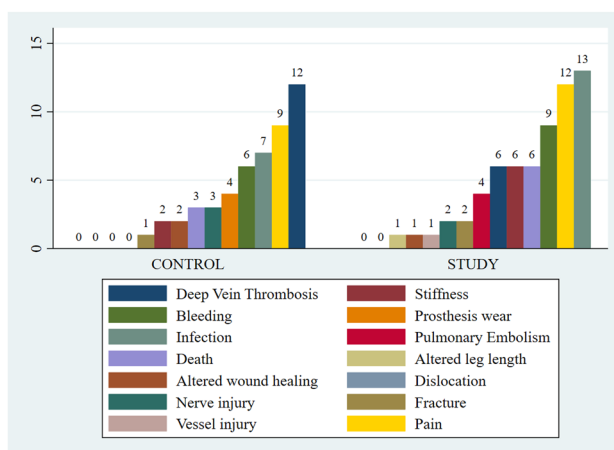


Fig. 1 Risk recall frequency in the groups

Patient satisfaction with the consent process was high in our whole cohort. However, the intervention group had a significantly higher satisfaction score despite one of the patients stating that they were overall unsatisfied with the process. Although the difference might be small in this study (0.8/10 or 8%), the figure may prove more significant when considering its effect in a national or international setting with higher patient numbers. Our findings are in keeping with those of Kaller et al., who investigated the differences in patient demographics and satisfaction between subjects who underwent IC pre-abortion versus those who consented via a telemedicine consultation [24]. Their findings indicated that telemedicine participants had higher odds of being very satisfied with the consultation and were more comfortable asking questions. Schallhorn et al. compared the quality of the consent process in refractive surgery between patients who had a preoperative teleconsent session and those who had an in-person session with their surgeon [25]. There was no significant difference in satisfaction between the patients who chose the telemedicine consent approach versus those who had an in-person consultation. They also stated that remote consent provided advantages over in-person sessions, including flexibility in managing timetables and available locations. It is important to note that only two participants were unsatisfied overall with our study's consent process. Despite being in different groups, they both were in the ISCED [14] high education category. The issues they raised involved the excessive use of medical terms and the provision of too much information on the day of surgery. Patient anxiety and the advice to avoid excessive medical jargon are common issues that are highlighted in the literature [4]. It has been suggested that efforts should be made to determine the individual desires of patients regarding the amount and depth of information they receive regarding their treatment [4, 32]. A potential solution to this challenge has been the development of "Core Information Sets." [33] These information sets aim to provide patients with essential knowledge regarding a specific diagnosis or procedure and have been developed by consensus agreement between patients, health care workers, family members and support groups.

This study has some limitations: The group allocation was not blinded to the author who consented the participants before surgery. There also was no baseline evaluation of patient knowledge of the surgery they are undergoing. The authors acknowledge that risk recall only constitutes one element of informed consent and that other concepts are involved in patient understanding of the entire process. The strengths of this study are that all consent consultations were performed using the same BOA guideline [12]. This ensured consistency in the communication process and minimised the risk of information loss in consultations. Another vital strength was that demographic and educational attainment levels were similar in both groups, thus reducing the risk of

allocation bias. In the ideal situation, the continued use of teleconsent would be implemented in our institution in the long term for all patients, but due to resource constraints, it can only be used in a select few at present. There is ongoing research in our institution to optimise the consent process and language to improve patient understanding of their treatment options. Once this is completed, the combined findings from all studies will be used to implement change and improve overall patient experiences.

Conclusion

The use of an additional preoperative teleconsent and information session improved patient satisfaction with the IC process for KA but did not improve the overall risk recall rate. Our findings also suggest a patient's level of education may affect their ability to recall information discussed during the consenting process. We can advocate for the increased use of teleconsent and telemedicine in patients undergoing KA or any elective orthopaedic procedure due to its perceived positive effects on patient satisfaction rates. We do however concede that resource constraints may limit the widespread use of teleconsent in this setting. Finally, we recommend an approach to informed consent that is tailored to the specific information needs of patients within diverse cultural contexts.

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