Exposure-Related Anxiety and Improving Patient Satisfaction with Medical Undergarments During Surgery

A Randomized Controlled Trial

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Background: The standard of care for patients undergoing a surgical procedure is to have patients remove all clothing and don a hospital-provided gown. A growing number of patients have anxiety when exposing their bodies in a medical setting, which increases stress for those patients.

Methods: This study prospectively enrolled patients at a single orthopaedic specialty hospital into 1 of 2 garment groups in a block-randomized design. Patients were asked to remove all clothing; 100 patients received the standard-of-care gown only, and 100 patients received the standard-of-care gown plus a single-use undergarment designed with retractable panels and a releasable waistband. Patients completed surveys evaluating their levels of anxiety with regard to exposing their bodies in a medical setting.

Results: There were 181 subjects (91%) who completed the preoperative surveys and 166 subjects (83%) who completed the post-discharge surveys. Fifty-seven subjects (31%) reported being uncomfortable exposing their private, intimate parts in a medical setting, and 39 subjects (22%) reported experiencing stress and/or anxiety related to body exposure. Ninety-seven patients (54%) agreed or strongly agreed that protecting their personal modesty is important when undergoing a medical procedure. More patients in the undergarment group agreed or strongly agreed that the garments provided by the hospital met their expectation for privacy (80 patients [87%]), compared with the standard-of-care group (65 patients [73%]) ($p = 0.025$). Patients in the undergarment group (36 patients [39%]) were more likely than those in the standard-of-care group (16 patients [18%]) to strongly agree that they were satisfied with the hospital-provided garments ($p = 0.028$). When asked if the hospital-provided garments would influence their choice of hospital, patients in the undergarment group agreed or strongly agreed 3 times as often (19%) as the standard-of-care group (6.6%) ($p = 0.06$).

Conclusions: Exposure-related stress and/or anxiety are experienced by a substantial percentage of surgical patients, and the majority consider protection of their personal modesty in a medical setting to be important. The use of medical undergarments to protect modesty significantly increased levels of patient satisfaction.

Level of Evidence: Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

The medical examination gown has been standard attire for patients in the hospital setting for decades. The loose fit and open back provide for convenient access to most anatomic regions along with flexibility in patient positioning. The standard of care for a trip to the operating room in most surgical facilities requires patients to remove all personal clothing, including undergarments, wearing only the patient gown for coverage. The reasons for this requirement include maintaining hygiene and the integrity of the sterile field, the possibility of anesthesia-related incontinence, and allowing for rapid access to the groin and urinary tract, among others. However, the use of the patient gown without undergarments leaves patients with minimal coverage of private areas, which may lead to incidental exposure of patients' genitalia and buttocks throughout the care setting, and can be a major cause of anxiety for patients[1]. A recent study found that current

Disclosure: The **Disclosure of Potential Conflicts of Interest** forms are provided with the online version of the article (http://links.lww.com/JBJS/H104).

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patient gowns leave patients feeling vulnerable and exposed and having a diminished sense of identity, agency, and dignity[2]. Some patients even forego medical care because of pre-procedural exposure-related anxiety[3].

There is a growing movement in support of patient modesty for those patients who are uncomfortable with this exposure of their private anatomy for various personal and religious reasons. Those who have espoused a change in medical garment standards have claimed that this practice is unnecessary and have cited the lack of studies showing any change in clinical outcomes, such as infection and complication rates, when patients are permitted to wear their own undergarments. They also believe that the lack of undergarments, coupled with general anesthesia, creates an unnecessary loss of control for patients and a further imbalance in the patient-provider power dynamic. With dedicated websites, nonprofit organizations, and increasing coverage of patient modesty concerns in the lay press, a shifting standard may be approaching with regard to the established norms of surgical patient garments.

Single-use medical undergarments, such as the one evaluated in this study (COVR Medical), have been designed to allow for patient coverage beneath the medical examination gown. They feature retractable panels and a releasable waistband allowing for standard draping and access to surgical sites after patient positioning. The current literature discussing the preservation of patient modesty and privacy in the surgical setting has been severely limited. The purpose of this study was to measure exposure-related stress and/or anxiety in patients undergoing orthopaedic surgery and to determine if hospital garment selection impacts patient perception and satisfaction. We hypothesized that some patients would express stress and/or anxiety with exposing their private, intimate parts in a medical setting and that providing patients with surgical undergarments would improve their satisfaction and make them more likely to recommend the facility to friends and family.

Materials and Methods

Institutional review board approval was obtained prior to initiating this prospective, single-blinded, randomized controlled trial. The trial was prospectively registered at ClinicalTrials.gov (NCT05015569). All study participants provided informed consent obtained by a trained research coordinator for inclusion in this study. The informed consent process included a discussion indicating that the purpose of the study was related to perceptions and factors impacting patient dignity, but patients were blinded to the difference

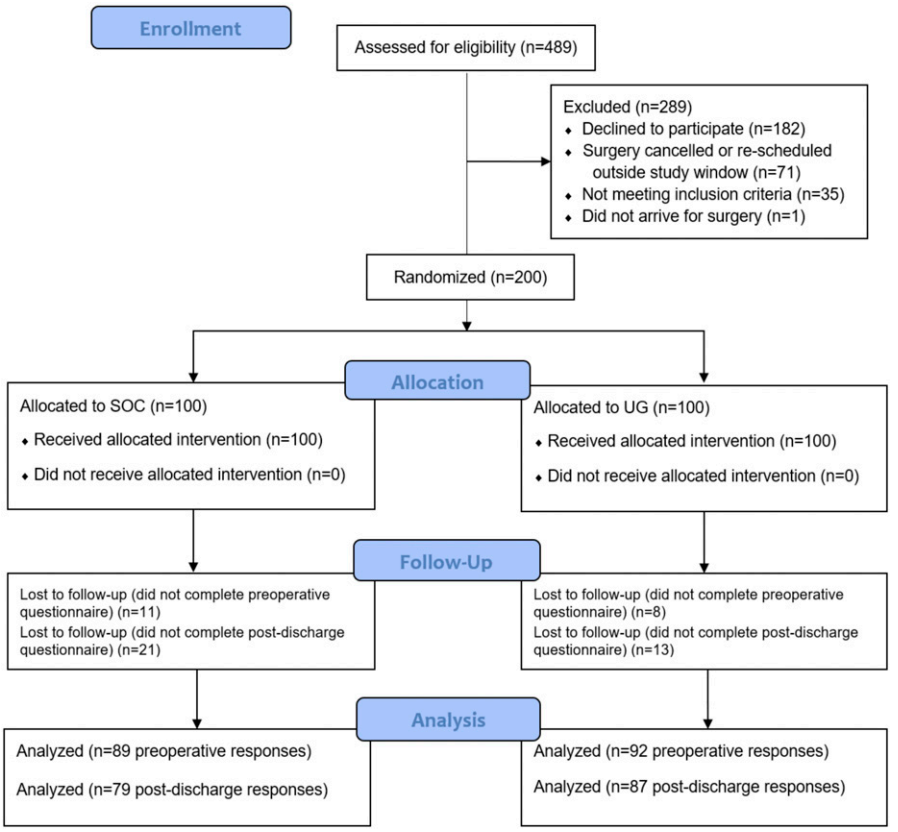

Fig. 1

CONSORT (Consolidated Standards of Reporting Trials) flow diagram for patient inclusion in the study. SOC = standard-of-care group, and UG = undergarment group.

TABLE I Patient Demographic Characteristics

	Standard-of-Care Group	Undergarment Group	P Value
Age* *(yr)*	63.8 ± 12.1	62.9 ± 14.0	0.68
Female sex	53%	62%	0.18
Body mass index* *(kg/m²)*	30.6 ± 5.6	30.3 ± 6.5	0.61
Underwent surgery prior to study	94%	88%	0.16

*The values are given as the mean and the standard deviation.

between garment groups. The research coordinator then followed the patients for appropriate randomization based on the predetermined method. A pre-study power analysis was performed to determine how many subjects would be required to detect a 1-point difference in median Likert scale responses between groups. As no prior data for this survey were available, the analysis assumed a relatively high standard deviation of 1.5 in each garment group, which was larger than the target group difference, to ensure that the study was not underpowered. The power analysis indicated that a sample size of 50 subjects per study arm would achieve a power of 0.90 based upon these assumptions. In order to account for a possible larger standard deviation as well as patient dropout, the target sample size was doubled to 100 per group.

Patients were enrolled at a single orthopaedic specialty hospital located in a major U.S. metropolitan area. They were block-randomized on the basis of the week of the surgical procedure to 1 of 2 garment groups; once 1 group reached 100 patients, all remaining patients were placed in the other group to maintain a 1:1 randomization. Both groups were asked to remove all clothing, including their undergarments. Patients in the standard-of-care control group received a patient gown only, in accordance with hospital standard operating procedures, and patients in the undergarment study group received the standard-of-care gown plus a single-use medical undergarment (COVR Medical) in the appropriate size. The garments contain retractable panels and hook-and-loop fasteners in key locations to allow for standard draping and access to surgical sites. Inclusion criteria were a patient age of ≥18 years; being scheduled to undergo a musculoskeletal surgical procedure of the upper extremity, lower extremity, or spine performed by an orthopaedic surgeon at the study site; the ability to speak, read, and understand English; and the ability to be enrolled within 3 weeks before the surgical procedure date. Patient exclusion criteria were unwillingness to provide informed consent, patient unwillingness to participate in surveys, patient body habitus outside of the COVR medical size range, a procedure not meeting the medical billing and coding definition of an orthopaedic surgical procedure, and patient incarceration at the time of the procedure.

A 7-question preoperative survey was administered by the research coordinator to all patients after they donned the hospital-provided garments in the preoperative area. Questions were designed to assess how patients felt about exposing their bodies in a medical setting, what their satisfaction level was with the garments provided by the facility, and whether hospital garments would impact their decision to recommend, or return to, the facility for a similar procedure. The key words in each question, such as exposure, modesty, privacy, dignity, and anxiety, were carefully selected from terminology that is commonly used in the growing literature on the patient modesty movement[1-3]. Each question was ranked on a 5-point modified Likert scale from "Strongly Agree" to "Strongly Disagree," with a "Neutral" midpoint. A second, 7-question, post-discharge survey was completed by study participants 2 to 6 days after leaving the hospital and was returned to the research coordinator. This subsequent survey used similar questions that were targeted at patient modesty and dignity but were phrased for patients to reflect on the feelings that they experienced during their time in the facility. These surveys were not validated as instruments through pilot or validation studies, but rather served to assess patients' impression of their exposure-related anxiety immediately before and several days after the procedure. General patient demographic characteristics were collected at the time of informed consent. The primary objectives of this study were to assess the impact of providing a medical undergarment in addition to the standard-of-care gown on patient anxiety and perception of modesty, dignity, and satisfaction.

Patient demographic and baseline variables were analyzed using descriptive summary statistics. The chi-square test

TABLE II Procedure Location by Garment Group*

Body Region	Standard-of-Care Group	Undergarment Group
Hand-wrist	0	1
Shoulder	13	14
Spine†	13	13
Hip	10	20
Knee	47	34
Foot-ankle	5	5
Other	1	5

*The p value between groups was p = 0.169. †Procedures of the cervical, thoracic, and lumbar regions were included in this study.

was used to determine the significance of differences in ordinal and categorical variables between groups. Statistical analysis was performed using JMP version 15 (SAS Institute). As the study included a mixture of lower-extremity, upper-extremity, and spine procedures, a post hoc subgroup analysis was used to ensure that surgical cohorts were well matched. Significance was defined as $p < 0.05$.

Source of Funding

COVR Medical, the manufacturer of the medical undergarments used in the study, provided funding for the study and undergarments for patient use in the study.

Results

In the first quarter of 2021, 200 patients were enrolled over a 4-week consecutive period into 4 alternating blocks (the standard-of-care group for weeks 1 and 3 and the undergarment group for weeks 2 and 4), with 100 patients randomized into the standard-of-care group and 100 patients randomized into the undergarment group. Patient recruitment concluded once 100 patients were placed in each group. A total of 181 subjects (91%) completed and returned the preoperative survey and 166 subjects (83%) completed and returned the post-discharge survey, with similar completion rates between groups: 89% for the standard-of-care group and 92% for the undergarment group preoperatively, and 79% for the standard-of-care group and 87% for the undergarment group post-discharge (Fig. 1). There were no significant differences in patient demographic characteristics (Table I) or the distribution of surgical sites between groups (Table II). Patients were excluded from analysis following randomization only if they failed to complete both of the surveys. Eleven patients in the standard-of-care group and 8 patients in the undergarment group declined to complete preoperative surveys after donning the provided hospital garments, and 21 patients in the standard-of-care group and 13 patients in the undergarment group were unable to be reached to return the post-discharge survey within the predetermined time period.

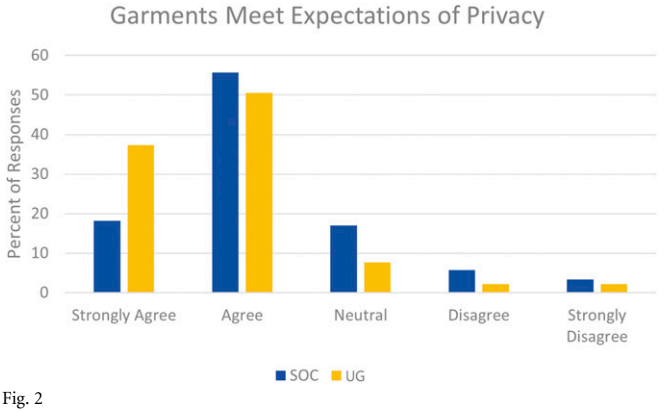

Fig. 2

Patient responses to preoperative question 3: The garments provided by the hospital meet my expectations for protecting my privacy. SOC = standard-of-care group, and UG = undergarment group.

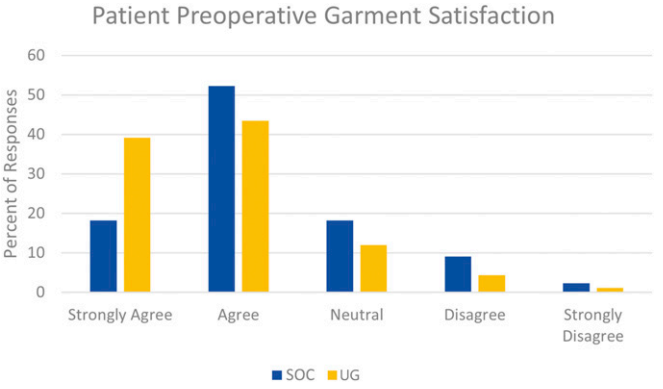

Fig. 3

Patient responses to preoperative question 4: I am completely satisfied with the garments provided by the hospital for my procedure. SOC = standard-of-care group, and UG = undergarment group.

Fifty-seven subjects (31%) reported being uncomfortable exposing their private, intimate parts in a medical setting, and 39 subjects (22%) reported experiencing stress and/or anxiety related to exposing their body. Ninety-seven patients (54%) agreed or strongly agreed that protecting their personal modesty is important when undergoing a medical procedure. No significant difference existed between the study groups in their exposure comfort ($p = 0.30$), anxiety related to exposure ($p = 0.55$), or ranking of importance of protecting personal modesty ($p = 0.64$), indicating that the groups were well matched.

A significantly higher number of patients in the undergarment group (80 patients [87%]), compared with the standard-of-care group (65 patients [73%]), agreed or strongly agreed that the garments provided by the hospital met their expectation for protecting their privacy ($p = 0.025$) (Fig. 2). Furthermore, the undergarment group ranked their satisfaction with the garments provided by the facility more highly ($p = 0.028$) than the standard-of-care group, with 36 patients (39%) in the undergarment group compared with 16 patients (18%) in the standard-of-care group strongly agreeing with the satisfaction question (Fig. 3). When asked if the garments provided by a hospital would influence their choice of hospital, patients in the undergarment group agreed or strongly agreed at nearly 3 times the rate (19%) as the patients in the standard-of-care group (6.6%) ($p = 0.06$). Similarly, there was a threefold increase in patients in the undergarment group (21%) who indicated that garments would influence their decision to recommend a hospital to family or friends compared with the standard-of-care group (6.7%) ($p = 0.051$).

The 2 groups were also well matched according to surgical anatomic location ($p = 0.169$).

Discussion

There is a dearth of peer-reviewed literature addressing patient modesty concerns and the impact that patient perception of privacy has on patient satisfaction. The concept

of patient dignity, which includes a component of modesty, has been better studied in the literature. Walsh and Kowanko interviewed a small sample of nurses (n = 4) and patients (n = 5) to identify key characteristics of patient dignity. There was general agreement between nurses and patients that dignity included concepts of privacy, which were further recognized as "privacy of the body." Privacy of the body was outlined as exposure of the body and protection from the gaze of others, specifically in undignified situations[4]. To our knowledge, this concept has not been explored in the orthopaedic literature.

Exposure-related patient anxiety was examined by Wetsch et al., with the authors finding that preoperative anxiety affects 45.2% of inpatients and 38.3% of outpatients[3]. A larger study of 100 patients in an Italian hospital created a 15-item patient dignity questionnaire divided into 3 sections focused on physical privacy, information and autonomy, and nurse-patient respectful interaction. Participants generally had positive scores for physical privacy, but the study noted that body privacy in some medical procedures was not completely preserved and that avoidable body exposure can be considered an important aspect of dignity[5]. Identifying ways to ease these levels of preoperative anxiety and maintain patient privacy may have positive effects on patient satisfaction and enhance the patient experience.

New offerings in the medical undergarment space such as Privacy Pants (Dignity Garment) designed primarily for colonoscopy, Comfort Care Premium Patient Gowns (ImageFIRST), and single-use surgical undergarments with appropriate anatomic access by COVR Medical are attempting to address the shortcomings of the patient gown and to improve the standard of care for patient physical privacy and dignity. Aamar et al. conducted a survey of patients asked to wear Privacy Pants for a colonoscopy procedure, finding that 76% of patients would request the garment over a standard gown. The study was nonrandomized and did not have a comparator group, but it did include a subset of patients who had undergone prior colonoscopy with a standard gown, reporting decreased embarrassment utilizing the new product[6].

Our study found that 31% of patients undergoing elective orthopaedic procedures admitted to feeling uncomfortable with the exposure of their body to the surgical and perioperative staff. Additionally, 22% of patients experienced increased levels of anxiety due to this discomfort. By providing single-use medical undergarments in addition to the standard gown, we found a significant increase in the reported patient satisfaction that the hospital met the patients' expectation of maintaining patient privacy. Furthermore, although the result did not reach significance, we found an interesting trend that the patients receiving medical undergarments as a part of the patient attire were almost 3 times more likely to indicate that they would choose to return to the same facility and recommend the facility to friends and family. These data indicate that offering medical undergarments to patients can help to ease perioperative stress and anxiety, maintain patient dignity, and improve the patient experience.

These results are generalizable to the population undergoing elective orthopaedic surgery, as the patient demographic characteristics were representative of community norms and there were no differences between the study groups. One of the weaknesses of this study was the lack of validation of the survey tools. Although the questionnaires were designed to measure various aspects surrounding patient dignity and the questions were directly related to their feelings and views, the lack of validation of the survey is a limitation. However, the validation of a survey in which subjects merely state their subjective feelings would be challenging. The lack of validation in our study was consistent with the methodologies used in prior studies evaluating exposure-related anxiety in the medical setting. Additionally, the sample size was not large enough to explore how patient responses may have varied by sex, age, surgical site, or other important factors that might influence patients' privacy experience. Although there appear to be several perceived benefits from the patient perspective, these garments will add marginally to the total case cost for the facility, and the cost-benefit relationship was not addressed through this study design. We had excellent participation rates, with 91% of patients completing the preoperative survey and 83% of patients completing the post-discharge survey, but the results may have been biased if the views of those declining to participate in 1 or both surveys were not representative. Lastly, the single-blinded nature of the study was a limitation. The research coordinator guiding patients through the survey was trained not to introduce bias; however, if the coordinator had also been blinded to the patient groups, it would have enhanced the validity of the study results.

Future research should be directed toward quantifying the extent to which patients' autonomy with respect to perioperative attire improves their experience and strengthens their sense of dignity, as well as what effect this may have on patient outcomes.

In conclusion, this randomized controlled trial demonstrated that exposure-related stress and/or anxiety are experienced by a substantial percentage of surgical patients and that the majority of patients consider the protection of their personal modesty in a medical setting to be important. When the hospital provided undergarments designed to protect modesty, patients were significantly more likely to report that the garments met their expectations of personal privacy and reported significantly higher levels of satisfaction with their garments. Patients in the undergarment group were almost 3 times more likely to indicate that they would choose to return to the same facility and recommend the facility to friends and family. Based on these findings, hospitals and providers should consider offering specially designed medical undergarments to reduce the exposure-related anxiety and concerns of patients. ■

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