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Effects of special waterproof layer under tourniquet cuff on the incidence of burns and pain intensity and satisfaction of operating room staff in knee arthroscopic surgeries: a randomized clinical trial

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Abstract

Introduction The use of multiple layers of vibril under tourniquet cuffs is common. However, these layers can lead to complications. We designed a special waterproof curtain for use under tourniquet cuffs. Its effects on burns, postoperative pain, and operating room staff satisfaction were evaluated.

Materials & methods In this randomized clinical trial, 34 patients underwent arthroscopic surgery of the knee joint in the operating rooms of selected hospitals at Isfahan University of Medical Sciences in 2022 via a simple random method. Even and odd days were divided into two groups: Group A (even days: special tourniquet drape: 17 people) and Group B (odd days: usual layers under the pneumatic tourniquet cuff: 17 people). The degree of pain was evaluated with a visual analog scale (VAS), the severity of burns was evaluated on the basis of a rating from one to four, and the satisfaction of the operating room personnel was evaluated via a standardized questionnaire with 10 questions.

Results Pain intensity was lower in Group A than in Group B at all times: immediately after recovery (2.29 ± 0.47 vs. 5.00 ± 0.71, $P < 0.001$), during the first eight hours (1.71 ± 0.47 vs. 3.94 ± 0.56, $P < 0.001$), during the second eight hours (2.82 ± 0.73 vs. 5.12 ± 0.45, $P < 0.001$), and during the third eight hours (1.65 ± 0.61 vs. 3.59 ± 0.62, $P < 0.001$). None of the participants in Group A and only one participant (5.9%) in Group B suffered burns, a difference that was not significant ($P = 0.5$). Most of operating room personnel (82.4%) reported a "high" level of satisfaction.

Conclusion The use of a special tourniquet in arthroscopic surgeries of the knee joint seems to have a positive effect, considering the reduction in postoperative pain and the increase in the level of satisfaction of the operating room personnel.

Keywords Arthroscopy, Knee, Tourniquet

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Introduction

Knee arthroscopy is one of the most common orthopedic surgeries and is used both for diagnosing and treating intra-articular pathologies [1]. The results of several studies have shown that, theoretically and clinically, the use of a tourniquet can reduce the amount of blood loss in this surgery [2, 3], and improving the surgeon's vision can lead to a reduction in operation time [4–10]. The most common complication of using a tourniquet is pain, which causes discomfort to the patient during the operation and affects the results of the operation [4, 11]. Tourniquet-related complications persist as a significant clinical concern, with evidence from the literature indicating that postoperative pain occurs in 35.8–60% of lower extremity surgeries and 51.8–60% of upper extremity surgeries, particularly when swelling extends beyond 60 min [1]. In addition, posttourniquet syndrome is a common reaction to prolonged limb ischemia in which the patient experiences stiffness and decreased muscle strength, pallor, dry joints, and a tingling sensation. Although this condition interferes with the postoperative physiotherapy program, it usually resolves itself approximately 24 h after surgery [2, 3].

In some studies, researchers considered the cause of such problems in typical tourniquets to be related to the layers beneath them and suggested replacing these layers with better materials [4–6]. Despite potential benefits in reducing blood loss, particularly in total knee arthroplasty (TKA), where tourniquets decrease intraoperative blood loss by 138–544 mL [7–9], the materials used under tourniquet cuffs may exacerbate complications. The use of conventional cotton pads, including 100% bleached pure cotton vibril and similar layers under the tourniquet cuff, can lead to leg pain and limb swelling [7], necrosis after orthopedic surgeries [12], skin peeling, wound hematoma leading to permanent wound drainage, and an increased risk of subcutaneous infection [1, 10, 11]. The complaints of thigh pain in patients for whom the usual layers of 100% bleached pure cotton vibril were used under the tourniquet cuff are probably due to blood congestion and fluid accumulation in the fabric or vibril tissue under the tourniquet cuff and, as a result, the direct pressure of the tourniquet. This pressure is localized on nerves and soft tissue; the swelling of the limb and the increase in the internal pressure of the soft tissue caused by the reperfusion reaction after release of the tourniquet may lead to pain in the operative field [12].

The absence of a specialized protective covering beneath tourniquet cuffs, such as nanoproducts, can result in various complications, increasing patient and hospital treatment costs. Therefore, there is a need to adopt newer, more accessible, and less expensive methods with fewer side effects. As such, there is a pressing need for a protective layer with the following attributes: waterproof and liquid-penetration resistance to prevent fluid accumulation; absorbent properties to manage minimal fluid leakage and prevent burns; and the ability to reduce pain and mitigate back syndrome [13]. Another issue is the satisfaction of personnel in cases involving the use of a tourniquet and its different types. The satisfaction of personnel with the tools and materials used in the work environment facilitates the improvement of the existing situation and enhances the efficiency of personnel in providing better medical care. In addition, the satisfaction of operating room personnel with the tools used in surgery is highly important, as facilitating the surgical process forms the basis for improving surgical outcomes and, as a result, reducing potential complications caused by surgery [13–16].

Considering that the leakage of liquids, especially blood, under the tourniquet in orthopedic surgery is very dangerous and, in some cases, causes various complications [5], and considering the role of operating room technicians in maintaining hemodynamics during surgery and providing solutions to prevent bleeding or its aggravation [3, 17], it seems necessary to design and replace a protective covering under the tourniquet. As mentioned before, first it should have waterproof and liquid-penetration properties, which, in the first place, will prevent water penetration and accumulation under the cuff. Second, it should absorb liquids, which, in the case of possible and minimal passage of liquids, will quickly absorb them and prevent the accumulation of liquids and burns in this area. Third, the use of a tourniquet should prevent complications caused by the tourniquet, especially pain and back syndrome. High availability, a reasonable price, ease of use, and high effectiveness are other features of this tool. The absence of such a cover can harm the patient by causing the various complications mentioned and therefore increase the costs of treating the patient and the hospital. For these reasons, we decided to use a special waterproof drape under the tourniquet in orthopedic surgeries to more accurately measure its possible side effects on the patient. The construction of the waterproof cover for the tourniquet under the cuff was completed according to the functional plan below.

According to Fig. 1, the waterproof cover for the tourniquet included two main parts, as follows:

> Part 1-The inner layer: is made of liquid-absorbing foam, which, in addition to being highly impermeable compared with the usual materials used in tourniquets (vibril), has high absorption power for fluids. This layer effectively absorbed the small amounts of fluid that passed through and pre-

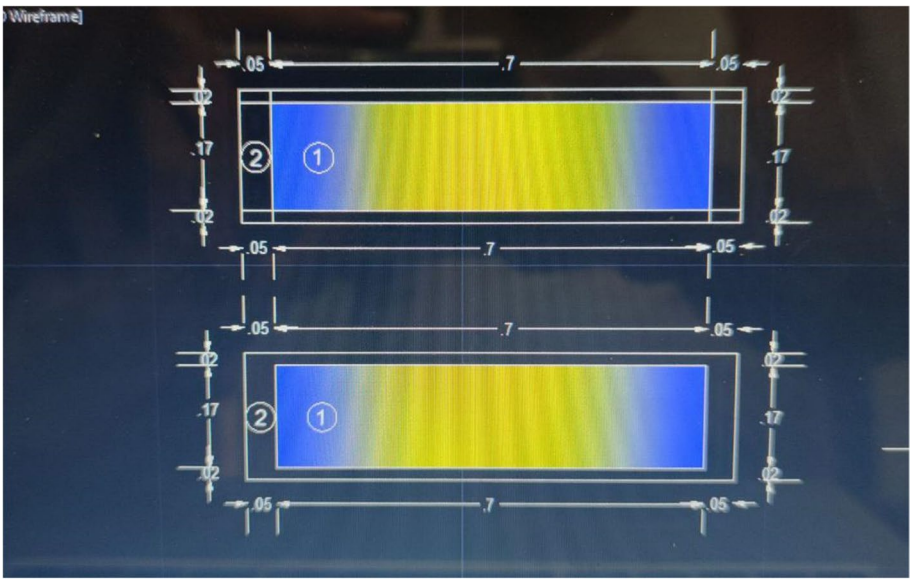


Fig. 1 Schematic diagram

vented their excessive accumulation under the tourniquet, thereby avoiding complications caused by these accumulations. This part was used in a rectangular shape with dimensions of 70 × 17 cm and was marked with the number"1"in the plan shown below (Fig. 1).

Part 2-Outer layer: In this part, two layers of adhesive were used as follows to create maximum adhesion to the patient's body, prevent liquids from penetrating, and avoid excessive sensitivity to the patient's skin:

This study addresses two underexplored aspects of tourniquet use: 1- the role of interface materials in preventing cutaneous complications and improving patient outcomes and 2- the impact of equipment design on the operating room workflow. We hypothesize that a waterproof absorbent layer beneath the tourniquet cuff will reduce postoperative burn incidence by 40%, decrease pain scores on the visual analog scale by ≥ 2 points, and increase staff satisfaction ratings by 30% compared with conventional cotton padding. By systematically evaluating both clinical outcomes and ergonomic factors, this investigation aims to provide evidence-based recommendations for optimizing tourniquet use in ambulatory orthopedic procedures. Notably, this waterproof cover was designed and approved by the researcher of this project in another study. This study was designed and conducted in alignment with the CONSORT checklist guidelines [18].

Methods

This randomized clinical trial was conducted in the form of a randomized clinical trial with a blind statistical analyzer. The statistical population of this study included all patients who underwent arthroscopic surgery of the knee joint in the operating rooms of selected hospitals at Isfahan University of Medical Sciences in 2022 and met the inclusion criteria. The inclusion criteria were as follows: ages between 18 and 60 years old, both gender, informed consent, arthroscopic knee surgery requiring the use of a tourniquet, nonemergency surgery, no fractures in other body parts, no history of lower limb ischemia and no history of illness. Cardiovascular conditions such as congestive heart failure; cardiac arrhythmias; high blood pressure; diabetes; nondrug use; continuous alcohol or cigarette consumption of more than 5 packs per year; no chest, head, or abdominal trauma; no need for other surgeries; and no history of coagulation diseases or anticoagulant drugs. The exclusion criteria were as follows: the patient's unwillingness to continue cooperation at any stage of the research.

After the approval of the Ethics Committee of Isfahan University of Medical Sciences was obtained (ethics code: IR.ARI.MUI.REC.1401.115) and the proposal was registered at the Iranian Clinical Trial Center (IRCT) (registration number: IRCT20220718055487 N1), sampling was performed via random allocation. Sample size was estimated 17 each group, considering confidence interval of 95%, power of 0.9 and values from Tetro et al. study and attrition rate of 10% [19]. In this way, patients who

underwent operations on even days were in Group A (17 people), and patients who underwent operations on odd days were in Group B (17 people). At a coordinated time and place and in person, the demographic information checklist (age, sex, and body mass index) was completed via clinical records. In Group A, the tourniquet used was an inflatable tourniquet, beneath which four layers of vibril made of 100% pure cotton were used to protect the skin.

After creating the waterproof cover for the tourniquet (Fig. 2), its effectiveness and resistance were tested on the moulage with an outer layer of natural leather. To test and examine the product, after a specially designed waterproof cover under the tourniquet was used, the final product was placed in close proximity to the drinking water for 30 min. Finally, through observation and assessment of the amount of water penetration and accumulation under the tourniquet, its efficiency was verified and confirmed. Notably, this waterproof drape was produced and approved during another independent study at the research center of the Faculty of Nursing and Midwifery of Isfahan University of Medical Sciences, with the ethics code IR.ARI.MUI.REC.1400.080.

The tourniquet pressure in all patients was set at 150 mm Hg above the systolic pressure (270 to 300 mm Hg) [1]. Immediately after the surgery, the duration of the operation was recorded. Then, in the first 24 h after recovery, the patients were examined by the researcher in terms of the amount of pain (using the VAS scale, immediately, and every 8 h after recovery was initiated). On this scale, patients score the intensity of their pain from 0 (no pain) to 10 (highest pain intensity) [1].

The severity of the burn, in the first 24 h after recovery, was assessed by the researcher on the basis of the following grading system through observation and registration on the relevant checklist:

First degree: Involvement of the epidermis; red skin without blisters.
Second degree:

- *Superficial involvement of the dermis*: Red skin without blisters, which turns white when pressed.
- *Deep involvement of the dermis*: Red skin with blisters.

Third degree: Involvement of the entire skin; hard and white skin.
The fourth degree includes the entire skin and underlying muscle and bone layers and black and dry skin.

To measure the satisfaction of the operating room personnel, the standard personnel satisfaction questionnaire containing 10 items was used. These items were scored on a 5-point Likert scale (very low: 1 point, low: 2 points, medium: 3 points, high: 4 points, very high: 5

Fig. 2 The final product (special waterproof cover under the tourniquet cuff)

points). Scores between 10 and 15 were considered low satisfaction, scores between 16 and 34 were considered medium satisfaction, and scores between 35 and 50 were considered high satisfaction. The validity and reliability of this questionnaire was examined by our team, showing a Cronbach alpha 0.75. This questionnaire was completed by the researcher in the operating room after the surgery.

Notably, all the measurements and data recordings were conducted by one researcher, and all the surgical procedures were performed by one orthopedic surgeon and a single team under anesthesia.

Finally, the data were analyzed via the Friedman, t, Mann–Whitney, and chi–square tests with Statistical Package for the Social Sciences (SPSS) version 25.0 software and Stata software version 2.9 (Stata Corp., College Station, TX, USA). In all tests, the confidence level was 95%, and the significance level was set at less than 0.05.

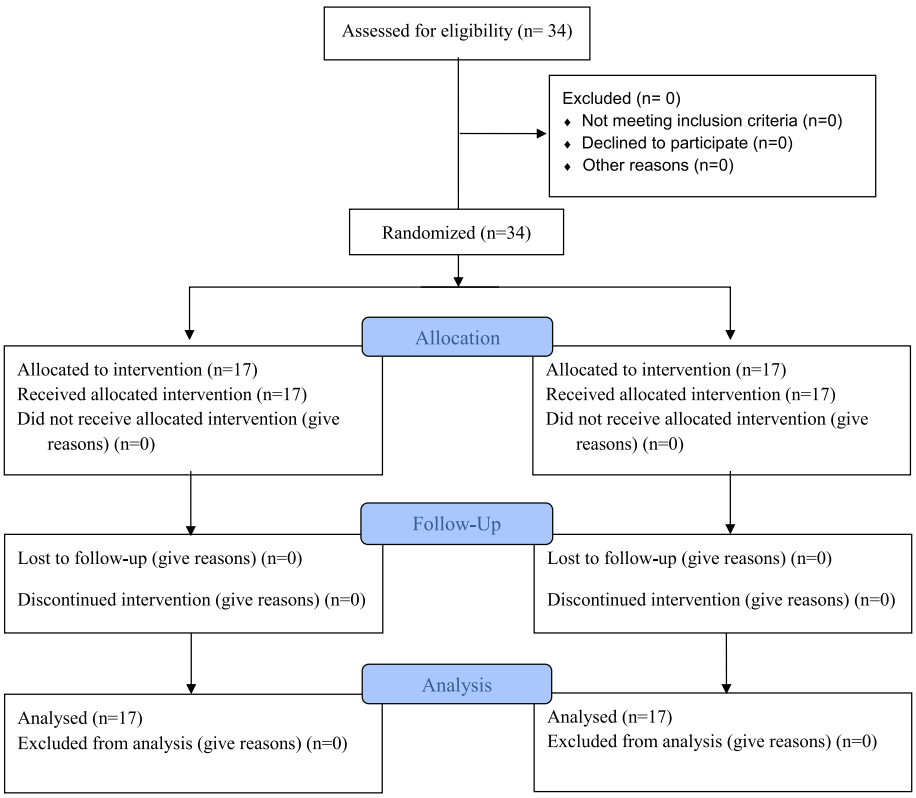
Results

According to the flow chart, no patients were excluded from the study. Compared with Group B, Group A was not significantly different in terms of age (32.94 ± 4.37 vs. 33.71 ± 4.67 years; $P = 0.999$) or BMI (28.59 ± 2.21 vs. 28.94 ± 2.73 kg/m^2; $P = 0.581$). Most of the participants in Group A (70.6%) and Group B (64.7%) were men. There was no significant difference between the sexes ($P = 0.714$) (Table 1).

The mean and standard deviation of the duration of surgery for patients in Group A was 139.12 ± 13.72 min, and in Group B, it was 135.59 ± 12.73 min; this difference was not significant ($P = 0.303$). According to Table 2, the intensity of pain in Group A was lower than that in Group B at all times—immediately after recovery, the first eight hours after recovery, the second eight hours after recovery, and the third eight hours after recovery.

In Table 2, the distribution of the severity of burns caused by the use of tourniquets in the studied groups is presented. On the basis of these data, none of the participants in Group A suffered burns. Only one participant (5.9%) in Group B experienced burns, which were first-degree burns. There was no statistically significant difference in the severity of burns between the studied groups ($P = 0.5$).

The mean and standard deviation of operating room personnel satisfaction with the special drape under the tourniquet used in this study was 41.71 ± 1.61 (out of 50 points) in group A vs. 33.82 ± 4.11 in group B. Statistical analysis showed significant higher values in group A ($P = 0.000$). Most of operating room personnel (82.4%) reported a"high"level of satisfaction with the special drape under the tourniquet used in this study.



CONSORT Flow Diagram

Table 1 Demographic characteristics

Variables		Group A		Group B		*P* value
		n	%	N	%	
Age (year)	18—29	4	23.5	4	23.5	0.999*
	30—60	13	76.5	13	76.5	
Sex	Male	12	70.6	11	64.7	0.714**
	Female	5	29.4	6	35.3	
BMI (kg/m^2)	18.5–24.9	9	52.9	6	35.3	0.581*
	25–29.9	6	35.3	8	47.1	
	30 ≤	2	11.8	3	17.6	

BMI Body mass index

* Mann–Whitney test

** Chi-square test

Table 2 Clinical outcome of the patients

Variables		Group A	Group B	*P* value
Duration of surgery (min) [Mean ± SD]		139.12 ± 13.72	135.59 ± 12.73	0.303*
Pain (VAS) [Median (IQR)]	Immediately	2.00 (2–3)	5.00 (4.50–5.50)	> 0.001**
	First 8 h	2.00 (1–2)	4.00 (4–4)	> 0.001**
	Second 8 h	3.00 (2–3)	5.00 (5–5)	> 0.001**
	Third 8 h	2.00 (1–2)	4.00 (3–4)	> 0.001**
	***P* value**	0.000***	0.000***	
Burn severity [Frequency (%)]	Grade 1	0	1 (%5.9)	0.500****
	Grade 2	0	0	
	Grade 3	0	0	
	Grade 4	0	0	
	No burn	17 (%100)	16 (94.1%)	
Operating room personnel satisfaction Score [Median (IQR)]		42 (42–42)	34 (32–37)	0.000**

SD Standard deviation, *IQR* Interquartile range

* Chi-Square test

** Mann–Whitney test

*** Friedman Test

**** Fisher's exact test

Discussion

Since the use of a tourniquet and the usual layers beneath it in arthroscopic surgeries of the knee joint can be associated with complications such as burns and pain intensity after the operation and, as a result, dissatisfaction among the operating room personnel, we decided to take a step toward increasing the effectiveness of tourniquets and reducing the human and financial costs caused by the complications of using tourniquets by designing a special waterproof tourniquet drape. Therefore, the aim of the present study was to investigate the effects of using a special tourniquet on the incidence of burns, the intensity of pain after the operation, and the satisfaction level of operating room personnel in arthroscopic surgeries of the knee joint in selected hospitals at Isfahan University of Medical Sciences in 2022.

In our study, we employed a pneumatic tourniquet with specialized layers during arthroscopic knee surgery to enhance patient protection and comfort. Considering the number of reported cases of pain caused by tourniquets in surgical operations, the use of a special tourniquet drape could be a new step in overcoming this common complication in surgical operations. Similarly, Lai et al. investigated the effects of tourniquet use on postoperative pain, blood loss, recovery, and tourniquet burns in knee arthroscopy. The results revealed that the

intensity of pain after surgery was significantly greater in the tourniquet group [2]. Ahmed et al. reported that the application of tourniquets in knee surgical procedures is frequently associated with an increase in postoperative pain. However, their findings also highlighted that adjustments aimed at minimizing ischemia or reducing pressure may alleviate such adverse effects [6]; providing indirect support for the conclusion that enhanced tourniquet designs can contribute to pain reduction. In contrast, Migliorini et al. concluded in their study that knee arthroplasty performed without the use of a tourniquet generally yields superior overall outcomes [20]. In Migliorini's study the absence of a tourniquet group demonstrated the lowest incidence of deep vein thrombosis (DVT) and achieved the lowest Visual Analog Scale (VAS) pain scores at 24–48 h, as well as at 1, 3, and 12 months postoperatively. This group also exhibited the greatest improvement in range of motion at 3 days, 1 week, 1 month, 3 months, 6 months, and 12 months of follow-up, alongside the highest Knee Society Score (KSS) ratings at 1, 3, and 12 months of follow-up. Among the evaluated outcome data, the straight leg raise test results were significantly inconsistent; thus, no definitive recommendations can be derived from this test. Of course, in a number of studies, the effects of using a tourniquet and its various types on pain caused by surgery have not been fully confirmed. For example, Zhang et al. investigated the use of tourniquets in primary total knee arthroplasty. The results of this study revealed that there was no statistically significant difference in pain intensity among any of the studied groups [21, 22]. The reason for these contradictory results could be related to differences in how research units were investigated and the statistical sample sizes of the different studies.

Another reported complication related to the use of tourniquets in arthroscopic surgeries of the knee joint is local burn caused by the tourniquet. Regarding this issue, the results of the present study revealed that although none of the participants in Group A with a special tourniquet drape suffered burns caused by the use of tourniquets, there was no statistically significant difference in the severity of burns between the two groups. This lack of significance could, of course, be related to the small sample size of our study. It is possible that by increasing the sample size and conducting the study on a wider scale, a significant difference could be reported in this regard. However, the low prevalence of burns caused by tourniquets in this study is an important finding and a strong point for the use of a special tourniquet drape. This is because, in other studies, burns have been identified as important and common complications of tourniquet use during surgery. The results of other studies have also shown that the layer beneath the tourniquet is important for preventing the leakage of washing liquid under the tourniquet, as such leakage may cause severe skin reactions, local burns, and even the loss of part or all of the skin [23].

Other authors have suggested the use of a sterile towel, a piece of plastic, or even a surgical glove or premade devices pushed under the tourniquet to prevent burns caused by the tourniquet. However, these methods are incomplete and require more modern solutions [23]. This topic has been well addressed in the present study. With the design and use of a special tourniquet drape, none of the participants in Group A experienced burns caused by the tourniquet. This highlights the importance and high efficiency of special tourniquet drapes. In a contradictory study investigated the effect of using tourniquets in orthopedic surgeries. The results revealed that there was no difference in the occurrence of complications such as burns between the two investigated groups [14]. These differences could be due to variations in the tools and methods used to measure burn severity, as well as the demographic differences among the patients investigated in different studies.

In addition to the reduction in side effects (pain and burns), another important parameter that can indicate the efficiency of the tool used is the satisfaction of personnel with using that tool. In this context, the findings of the upcoming study revealed that most of operating room personnel (82.4%) reported a"high"level of satisfaction with the special drape under the tourniquet used in this study. Another positive aspect of using this drape in arthroscopic knee surgeries is that, in other studies, most operating room personnel were not satisfied because of issues such as the difficulty of applying the usual layers under the tourniquet or the occurrence of numerous related complications, especially pain and burns. For example, in the study of Lai et al. in China, by examining the effects of tourniquet use on postsurgery pain, blood loss, recovery, and tourniquet burns during knee arthroscopy, they concluded that the use of tourniquets during knee arthroscopy increased postoperative pain and prolonged postoperative recovery, thus causing dissatisfaction among the surgeon, operating room personnel, and patients [2].

Notably, some studies have reported that the use of tourniquets has no effect on the satisfaction of operating room personnel. For example, one study investigated the effects of tourniquet use in knee arthroplasty on the satisfaction of operating room personnel, muscle strength, and joint function of patients after surgery. The results revealed no difference in any of these parameters, especially the satisfaction of the operating room personnel, between the two groups [13]. These contradictions could be due to the demographic differences of the research

units in different studies, as well as differences in the statistical sample sizes of various studies.

In addition to the strengths of this research, this study, like any other study, also has several limitations. One of these limitations is the relatively small volume of statistical samples, which is due to the limited number of cases of knee arthroscopy or the use of tourniquets in selected hospitals in Isfahan. Owing to the limitations of our center, we were unable to include more participants than the number specified in our article. In future studies, we will strive to include a larger sample size to further strengthen the validity and generalizability of our results. Additionally, many known and unknown factors may have influenced the results of this study. Future studies on wider statistical populations will help clarify these factors further.

Conclusion

In conclusion, the findings of this study demonstrate that the use of a specially designed waterproof drape under tourniquet cuffs during knee arthroscopic surgeries significantly reduces postoperative pain intensity and enhances operating room staff satisfaction. Its potential to mitigate complications, enhance efficiency, and simplify surgical procedures supports broader adoption in clinical settings. Considering its high market demand and demonstrated benefits, further large-scale studies are encouraged to confirm these results and explore the full scope of its advantages.

Abbreviations

VAS Visual Analog Scale
IRCT Iranian Clinical Trial Center

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Ethical issues

This waterproof drape was developed and validated as part of a separate independent study conducted at the research center of the Faculty of Nursing and Midwifery, Isfahan University of Medical Sciences. Furthermore, this approval is reinforced by the issuance of the ethical code IR.ARI.MUI.REC.1400.080 and the formal registration of the study with the Iranian Registry of Clinical Trials under the registration number IRCT20220718055487 N1.

Authors' contributions

S.B. and M.T. designed the study and conducted the experiments. N.R. analyzed the data and contributed to the methodology. M.H.B. provided additional insights and contributed to the writing of the manuscript. S.Y.A. is the corresponding author and oversaw the entire project. All the authors reviewed and approved the final manuscript.

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Data availability

Data will be provided upon request from the corresponding author.

Declarations

Consent for publication

All the authors are aware of and have provided their consent for the publication of this manuscript. Patients who were fully aware and provided informed consent were included in our study.

Competing interests

The authors declare no competing interests.

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