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ORIGINAL RESEARCH

Value of HFMEA-based Predictive Care Combined With Multimodal Analgesia in Improving Rehabilitation After Orthopedic Internal Fixation Implantation

Xiaojing He, MD; Ailin Dang, MD; Fang Wen, MD

ABSTRACT

Context • Orthopedic internal fixation implantation (OIFI) is a frequently adopted surgery for fractures, but it can trigger various adverse reactions and increase patients' risks of postoperative complications. Reducing those risks is paramount for obtaining better therapeutic effects for OIFI.

Objective • The study intended to analyze the value of predictive nursing, based on healthcare failure modes and effects analysis (HFMEA), and combined with multimodal analgesia for improving postoperative rehabilitation after orthopedic internal fixation (OIFI), with the aim of offering reliable, accurate, and novel ideas and directions for future clinical OIFI and prognosis improvement for patients.

Design • The research team designed a retrospective analysis.

Setting • The study took place in the Department of the Operating Room at Hefei First People's Hospital in Hefei, Anhui, China.

Participants • Participants were150 patients who needed OIFI at the hospital between January and December 2020.

Intervention • Participants were assigned to one of two groups, 87 to the intervention group, who received treatment with HFMEA-based predictive care combined with multimodal analgesia after OIFI, and 63 to a control group who received routine nursing combined with multimodal analgesia after OIFI.

Outcome Measures • Postintervention, the study measured the effective treatment rate, risk priority number (RPN)—the severity, possibility, and detectable degree of the risk, analgesic effects, self-controlled delivery times, tumor necrosis factor alpha (TNF-α) and interleukin 6 (IL-6) levels, and incidence of adverse symptoms. Also postintervention, the participants completed a visual analogue scale (VAS) to indicate their satisfaction with the nursing as well as the Exercise of Self-care Agency (ESCA) scale and the Spielberger State-trait Anxiety Inventory (STAI).

Results • The study found significant differences between the groups. The intervention group showed significantly lower RPN values, VAS scores for analgesia, TNF-α and IL-6 levels, and incidence of adverse symptoms and also indicated greater satisfaction with the nursing, a significantly higher ESCA score, and a significantly better psychological state.

Conclusions • HFMEA-based predictive care combined with multimodal analgesia can substantially lower the risk and pain levels of patients undergoing OIFI and can improve their nursing experience and self-care ability, so it's worthy of clinical application, having great significance for patients' rehabilitation. (*Altern Ther Health Med.* 2022;28(8):38-45).

Xiaojing He, MD, physician; **Ailin Dang,** MD, physician; and **Fang Wen,** MD, physician; Department of the Operating Room, The First People's Hospital of Hefei, Hefei, Anhui, China.

Corresponding author: Ailin Dang, MD
E-mail: dzlybfch1@163.com

Orthopedic diseases are commonly seen traumatic diseases that mainly manifest with pain and dysfunction.[1] Without timely therapy, the disease is likely to trigger limb dysfunction and compromise patients' life quality.[2]

Fracture is a common condition in the orthopedics department and can trigger deformity in the affected part and limit activities.[3] Some patients with it even suffer shock due to extensive soft-tissue injury, massive hemorrhaging, severe pain, or complicated visceral injury.[2] Timely and effective treatment for fracture can help patients recover their functions to the maximum extent.[3] Therefore, the three basic principles of restore the original state of the bones, fixation of fractures, and rehabilitation training are of crucial importance in fracture treatment.[4]

Orthopedic internal fixation implantation (OIFI) is a frequently adopted surgery that helps patients by using fracture reduction and internal fixation with steel plates, steel

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needles, intramedullary needles, and screws.[6,7] It has advantages such as providing high treatment efficiency and contributing to a quick recovery.[8]

However, OIFI is very invasive, painful, and traumatic and can damage a patient's physical function to a certain extent.[9,10] It can trigger various adverse reactions, and patients are likely to suffer postoperative infections and severe pain and can face a higher risk of postoperative complications, which can compromise the treatment's effects and result in an unfavorable prognosis.[9-12]A series of stress factors such as pain, surgery, and trauma can intensify the release of inflammatory mediators and give rise to more severe illness and a higher risk of infection, which is highly unfavorable for patients' recoveries.[13]

Accordingly, infection prevention is of profound value to rehabilitation after OIFI, and reducing the risk of complications and an adverse prognosis due to adverse reactions is paramount for obtaining better therapeutic effects for OIFI. Reasonable analgesia technology is crucial for relieving patients' physical pain and improving the therapeutic effects.[14] It's paramount to allow patients to experience early painless activities using multimodal analgesia (A variety of analgesic drugs and methods with different mechanisms of action are combined to make them exert the best analgesic effect) to improve their rehabilitation, cooperation with treatment, and satisfaction.[15]

According to Yu et al's study, healthcare failure mode and effect analysis (HFMEA) is a systematic and forward-looking quality-management mode,[16] with positive effects on risk prevention. The intent of HFMEA-based predictive care is to prevent adverse reactions, analyze the possibility of risk factors through active and in-depth understanding of diseases, and then take corresponding preventive measures for each patient in the light of past experience, thus increasing the safety and effectiveness of treatment.[17] Shih MC et al have pointed out the profound value of HFMEA-based predictive care in reducing the error rate of preoperative preparation for arterial embolectomy.[18]

HFMEA-based predictive care can be helpful in reducing complications and patients' negative emotions and stress, guiding patients in learning basic nursing skills to obtain a stronger self-care ability, and providing patients with a good hospital environment and maximized comprehensive nursing services to help them recover faster.[19]

In addition, predictive nursing, a kind of advanced nursing, can help nurses to foresee and judge possible risks in light of previous nursing experience as well as use of relevant literature.[20] It can improve treatment quality and allow nurses to take preventive measures against possible adverse symptoms.[21,22]

The current study intended to analyze the value of predictive nursing, based on HFMEA and combined with multimodal analgesia, for improving postoperative rehabilitation after OIFI, with the aim of offering reliable, accurate, and novel ideas and directions for future clinical OIFI and prognosis improvement for patients.

METHODS

Participants

The research team designed a retrospective analysis. The study took place in the Department of the Operating Room at Hefei First People's Hospital in Hefei, Anhui, China. Potential participants were patients at the hospital who needed OIFI between January and December 2020. All the study subjects were patients in the orthopedics department of our hospital, and a retrospective analysis was carried out after screening according to the inclusion and exclusion criteria. The data of all patients were collected by Xiaojing He, and statistical analysis was performed by Ailin Dang.

Potential participants were included if: (1) Surgeons had confirmed through CT that they needed OIFI, (2) their detailed case data were available, and (3) they had no contraindications for the drugs and operation.

Potential participants were excluded if they: (1) had abnormal liver or kidney function, (2) had comorbid tumor diseases or cardiovascular or cerebrovascular diseases, (3) had autoimmune dysfunction, (4) were mentally ill, or (5) were unwilling to participate in the study.

After screening according to the inclusion and exclusion criteria, we identified 150 patients as study subjects.

The ethics committee of the hospital approved the study's protocols, and all participants signed written informed consent forms. This experiment was carried out strictly in accordance with the Declaration of Helsinki.

Procedures

Grouping. 87 cases were treated with HFMEA-based predictive care combined with multimodal analgesia after OIFI as the intervention group, while the other 63 were treated with routine nursing combined with multimodal analgesia after it as the control group.

Specific nursing measures. An HFMEA management group was set up with six staff members, including head nurses and nurses with more than five years of clinical experience, under the guidance of the director of the department.

First, the management group organized weekly training for the operating room's nurses, including specialized disease knowledge, disease-related nursing knowledge, catheter-related nursing knowledge, analgesia-related knowledge, and skill standards for operations. The management group also developed emergency nursing measures for prevention of adverse events during fracture rehabilitation, and the head nurse conducted an assessment of relevant knowledge after the training.

Second, the management group intensified health-associated education for participants. The group evaluated participants and their families to determine their education levels and knowledge about surgical catheters and conducted the targeted health education based on the results. The management group conducted that education mainly by centralized explanation (That is, imparting knowledge to patients and their families). After the explanation, participants received pictures and texts about that knowledge. For participants with low education levels or incomplete

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understanding of catheter use, the management group could use face-to-face communications, and demonstrations could occur to explain the method that a participant should use in placing the catheter when turning over, coughing, and going out for an examination.

Third, the management group arranged for the nursing staff to have more communication than usual with participants (For example: chat with the patient for more than 10 minutes every day, and ask the patient about the change in feeling during the treatment.), and the group developed a picture album for the hospital and operation environment for participants' use. Before surgery, the nursing staff introduced information about the hospital, disease-associated knowledge, examples of successful treatments, information related to the anesthesia on the operation day. Also, the nursing staff informed participants about possible adverse events and identified corresponding countermeasures, to soothe their anxiety and improve their psychological states.

After the operation, the staff explained information related to and precautions about the use of the analgesia pump to avoid any potential secondary injury.

Anesthesia. Prior to the start of surgery, every participant was given an L3-4 epidural and subarachnoid blockade in a lateral position. Specifically, 2-3 mL of 0.5% bupivacaine was injected into the subarachnoid space, and an epidural catheter was placed, with the level on the spine controlled below T12.

In the case of an incomplete blockade, 0.375% ropivacaine and 1% lidocaine were additionally injected into the epidural cavity. After determination of the anesthesia level, the participant received 50 mg of flurbiprofen axetil, infused intravenously, prior to the operation and was also given 0.1 μg/kg of sufentanil via epidural injection.

After surgery, the participants were given the same analgesia treatment as prior to surgery and were also given fentanyl through self-controlled intravenous analgesia, with an intravenous load of 50μg of fentanyl, a background infusion rate of 2 mL/h, a self-controlled intravenous analgesia in the amount of one mL, and a locking time of 15 min.

Outcome measures. At baseline and postintervention, the research team measured the effective treatment rate, risk priority number (RPN)—the severity, possibility, and detectable degree of risk,[23] analgesic effects, self-controlled delivery times, tumor necrosis factor alpha (TNF-α) and interleukin 6 (IL-6) levels, and incidence of adverse symptoms. At baseline and postintervention, participants also completed a visual analogue scale (VAS) to indicate their satisfaction with the nursing as well as the Exercise of Self-care Agency (ESCA) scale and the Spielberger State-trait Anxiety Inventory (STAI).[26,27]

Intervention

Control group. Each participant received routine nursing services, including an explanation of the significance and function of and precautions for self-controlled analgesia. The nurses regularly checked on participants and paid attention to the risks that could cause adverse nursing events, including postoperative infection and falling out of bed. In addition, the nursing staff instructed participants about matters needing attention during activities in rehabilitation (For example: avoid weight bearing, strenuous exercise, poor eating habits, etc.) and told them to return to the hospital regularly for reexamination.

Intervention group. Each participant received HFMEA-based predictive care. Before the intervention, all nursing staff received training on HFMEA-associated knowledge to ensure that they were proficient in the relevant knowledge. The nursing team summarized, analyzed, and discussed cases of adverse events among participants during their hospitalizations, using related research and their past experiences, and identified key matters needing attention in the nursing process.

Outcome Measures

Effective treatment rate. The study evaluated the effectiveness of the treatments, identifying participants as being healed, significantly improved, or not improved. Healed: Full recovery of pre-injury mobility after treatment. Significantly improved: Clinical symptoms improved, but mobility was still affected. Not improved: No effect.

RPN values.[23] The study evaluated postoperative RPN values for the groups from the perspectives of pain, postoperative posture management, rehabilitation exercise, drug use, and diet management. RPN evaluates the safety of patients during treatment from multiple perspectives. The higher the RPN value, the more likely the patient will have risk events and the lower the safety.

Analgesic effects and number of self-controlled doses.[24] Pain relief for patients after OIFI is the focus of modern clinical care. The research team performed a detailed assessment of postoperative pain changes in both groups, evaluating pain from 0 to 24 hours after surgery using a visual analogue scale (VAS) and also analyzing the number of self-controlled doses that participants used. The VAS score is divided into 1-10 points, and the higher the score, the more obvious the pain.

TNF-α and IL-6 levels. These levels are the main cause of complications after OIFI, and the increased postoperative inflammatory response is an indicator worthy of attention. The higher the test result, the more severe the patient's inflammatory response.

Incidence of adverse symptoms. For example: wound infection, prolonged infection, swelling, dizziness and nausea, and bone nonunion.

Nursing satisfaction.[25] Participants indicated if they were very satisfied, satisfied, or dissatisfied with the nursing they received. A scoring survey (out of 10 points) was conducted when the patients were discharged from the hospital, with 10 points being very satisfied, 6-9 points being satisfied, and less than 6 points being dissatisfied.

ESCA.[26] Modern clinical nursing is not only the rehabilitation nursing for the disease itself but also an extremely important link in the improvement of a patient's

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Table 1. Effective Treatment Rates Postintervention for the Intervention and Control Groups (N = 150)

	n	Healed n (%)	Significantly Improved n (%)	Not Improved n (%)	Total Effective Rate n (%)
Intervention group	87	62 (71.26)	24 (27.59)	1 (1.15)	86 (98.85)
Control group	63	38 (60.32)	22 (34.92)	3 (4.76)	60 (95.24)
χ^2					1.837
P value					0.175

Table 2. Comparison Postintervention of RPN Values Between the Intervention and Control Groups (N = 150)

	Pain Mean ± SD	Postoperative Posture Management Mean ± SD	Rehabilitation Exercise Mean ± SD	Drug Use Mean ± SD	Diet Management Mean ± SD
Intervention group	79.53 ± 5.43	68.91 ± 7.12	89.06 ± 5.83	70.13 ± 8.02	68.74 ± 8.57
Control group	178.69 ± 8.93	231.35 ± 12.34	200.23 ± 10.98	167.36 ± 9.28	136.71 ± 7.39
t	84.310	101.700	80.170	68.580	50.75
P value	<.001[a]	<.001[a]	<.001[a]	<.001[a]	<.001[a]

[a]$P < .001$ for all variables, indicating significantly lower risk in the intervention group than in the control group

Abbreviations: RPN, risk priority number.

self-care ability. The scale has four subdimensions: self-care, self-concept, self-responsibility, and health knowledge The higher the score, the stronger the patient's self-care ability.

STAI.[27] Divided into S-AI and T-AI, each dimension has 20 items, and the higher the score, the more serious the negative psychological state.

Statistical Analyses

The study used GraphPad Prism 9 (MSC.Software, Los Angeles, California, USA) for statistical analysis and graph drawing. Counting data (n/%) were analyzed using the Chi-square test, and enumeration data, means ± standard deviations (SDs), were analyzed using the independent-samples *t* test and repeated measures analysis of variance (ANOVA) as well as the least significant difference (LSD) post-hoc test. $P < .05$ denoted a significant difference.

RESULTS

Of the 150 participants, 87 were included in the intervention group, while 63 were included in the control group.

Treatment Efficacy

No statistically significant difference existed in the total effective rate between the two groups (Table 1). In both groups, treatment for most participants was effective, 71.26% for the intervention group versus 60.32% for the control group, and only 1.15% of participants in the intervention group had no improvement compared to 4.76% in the control group.

The RPN results for pain, posture management, rehabilitation exercise, drug use, and diet management (Table 2) in the intervention group were significantly lower than those in the control group, with $P < .001$ for all variables, which suggests that the intervention group's postoperative safety was higher.

Analgesic Effects

The VAS scores of control group had increased at 4h after surgery a compared with one hour after surgery ($P < .05$), There was no difference in the VAS score of the intervention group at 4h after operation and at 1h after operation ($P > .05$), indicating that participants began to experience obvious pain when the effects of anesthesia subsided (Figure 1). Subsequently, the scores of the two groups showed a trend of gradual decline and reached the lowest value at 24h after surgery ($P < .05$).

During this process, the intervention group's VAS score was significantly lower than that of the control group at all time points, with $P < .05$ (Figure 1A). Similarly, the number of self-controlled doses used in both groups increased significantly within the period from 1h to 4h after surgery compared with the period from baseline to 1h after surgery ($P < .05$).

The number of self-controlled doses in both groups remained relatively stable until the period from 8h to 16h after surgery ($P > .05$) and began to decrease during the period from 16h to 24h after surgery ($P < .05$). During the entire process (Figure 1B), the number of self-controlled doses for the intervention group was significantly lower than that in the control group ($P < .05$).

TNF-α and IL-6 Levels

The TNF-α and IL-6 levels weren't significantly different between the two groups at baseline (Figures 2A and 2B), but the levels increased significantly in both groups after surgery

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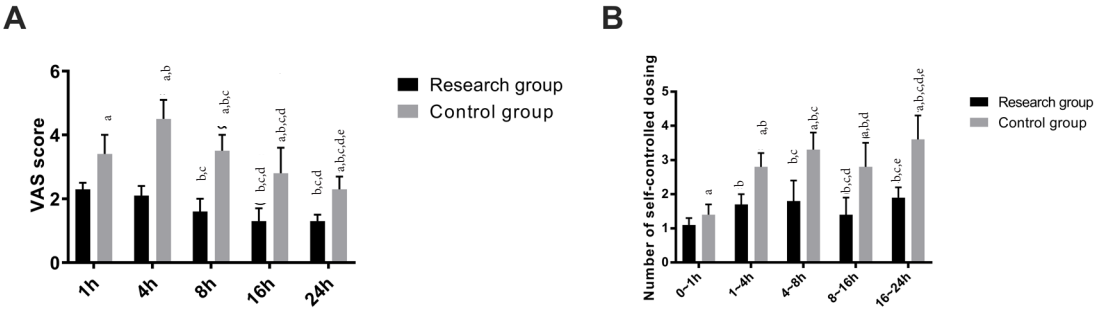
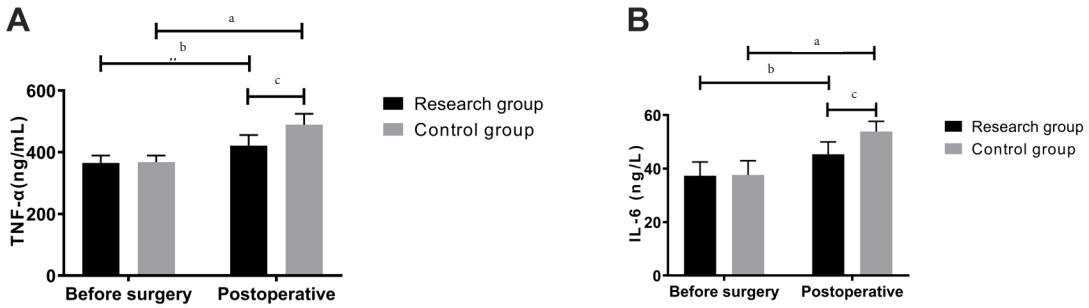
Figure 1. Comparison of Analgesic Effects and Number of Self-controlled Doses After Surgery Between the Intervention and Control Groups. Figure 1A shows the postoperative VAS scores, and Figure 1B shows the number of self-controlled doses



[a]* $P < .05$, indicating significantly lower VAS scores and number of self-controlled doses for the intervention group than for the control group for each of the time periods.
[b]# $P < .05$, indicates that there is a difference from 1h (or 0~1h).
[c]& $P < .05$, indicates that there is a difference from 4h (or 1~4h).
[d]@ $P < .05$, indicates that there is a difference from 8h (or 4~8h).
[e]$ $P < .05$, indicates that there is a difference from 16h (or 8~16h).

Abbreviations: VAS, visual analogue scale.

Figure 2. Comparison of Changes Between Baseline and Postintervention in the Levels of Inflammatory Factors for the Intervention and Control Groups. Figure 2A shows the changes in TNF-α levels, and Figure 2B shows the changes in IL-6 levels



[a]$P < .05$, indicating a significant increase between baseline and postintervention for the intervention group
[b]$P < .05$, indicating a significant increase between baseline and postintervention for the control group
[c]$P < .05$, indicating significantly greater increases between baseline and postintervention for the control group than for the intervention group

Abbreviations: TNF-α, tumor necrosis factor alpha; IL-6, interleukin 6.

Table 3. Incidence of Adverse Symptoms During the Study in the Intervention and Control Groups (N = 150)

	n	Wound Infection n (%)	Prolonged Healing n (%)	Swelling n (%)	Dizziness and Nausea n (%)	Bone Nonunion n (%)	Total Incidence n (%)
Intervention group	87	0 (0.00)	1 (1.15)	1 (1.15)	1 (1.15)	0 (0.00)	3 (3.45)
Control group	63	3 (4.76)	2 (3.17)	3 (4.76)	2 (3.17)	0 (0.00)	10 (15.87)
χ^2							7.126
P value							.008[a]

[a]$P = .008$, indicating significantly fewer adverse symptoms in the intervention group than in the control group

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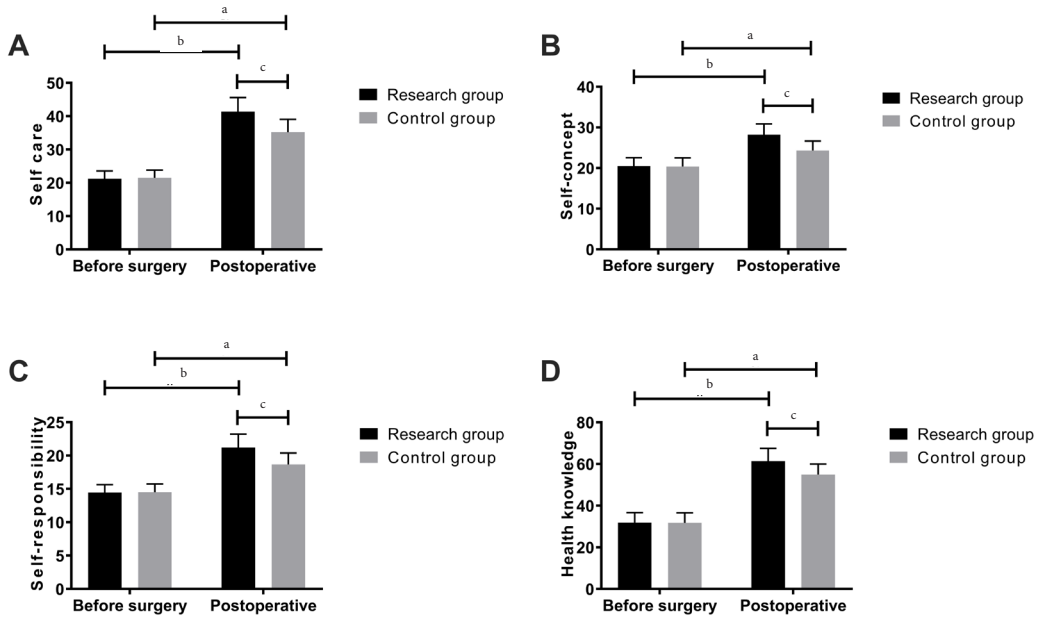
Table 4. Satisfaction Evaluation Postintervention for Intervention and Control Groups (N = 150)

	n	Very Satisfied n (%)	Satisfied n (%)	Dissatisfied n (%)	Total Satisfied n (%)
Intervention group	87	66 (75.86)	20 (22.99)	1 (1.15)	86 (98.85)
Control group	63	24 (38.10)	33 (52.38)	6 (9.52)	57 (90.48)
χ^2					5.760
P value					.016[a]

[a]*P* = .016, indicating significantly higher satisfaction in the intervention group than in the control group

Figure 3. Comparison of Changes in Self-care Ability Between Baseline and Postintervention for the Intervention and Control Groups. Figure 3A shows the self-care scores; Figure 3B shows the self-concept scores; Figure 3C shows the self-responsibility scores; and Figure 3D shows the health knowledge scores



[a]*P* < .05, indicating a significant increase between baseline and postintervention for the intervention group
[b]*P* < .05, indicating a significant increase between baseline and postintervention for the control group
[c]*P* < .05, indicating significantly greater increases between baseline and postintervention for the intervention group than for the control group

(*P* < .05). The postoperative levels of TNF-α and IL-6 in the intervention group were 421.32 ± 34.51 ng/mL and 45.34 ± 4.61 ng/L, respectively, and were significantly lower than those in the control group (*P* < .05).

Incidence of Adverse Symptoms

Table 3 shows that the total incidence of adverse symptoms for the intervention group was 3.45%, which was significantly lower than the 15.87% in the control group (*P* = .008). The adverse reactions in the intervention group were prolonged healing, swelling, and dizziness and nausea, while wound infection and swelling were the main ones in the control group. No participants in the intervention group developed wound infections, but 4.76% of participants in the control group did, which was the most significant difference between the groups.

Satisfaction

Table 4 shows that the intervention group's total satisfaction was significantly higher than that of the control group (*P* = .016). The satisfaction survey showed that the intervention group was mainly very satisfied (75.86%), while the control group was mainly satisfied (52.38%). In addition, only 1.15% of participants in the intervention group were dissatisfied versus 6.52% in the control group.

Self-care Ability

For the ESCA scale, no significant differences existed between the two groups in the scores for self-care (Figure 3A), self-concept (Figure 3B), self-responsibility (Figure 3C), or health knowledge (Figure 3D) at baseline (*P* > .05). Postintervention, the intervention group's scores for all dimensions increased, with the self-care, self-concept, self-

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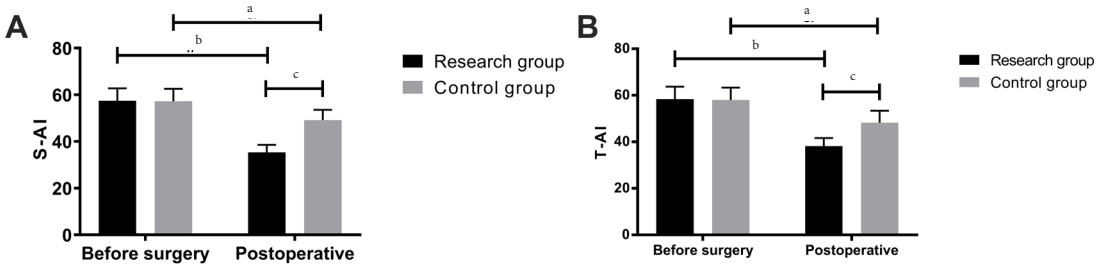
Figure 4. Comparison of Changes in Psychological State Between Baseline and Postintervention for the Intervention and Control Groups. Figure 4A shows the S-AI scores, and Figure 4B shows T-AI scores



[a]$P < .05$, indicating a significant decrease between baseline and postintervention for the intervention group
[b]$P < .05$, indicating a significant decrease between baseline and postintervention for the control group
[c]$P < .05$, indicating significantly greater decreases between baseline and postintervention for the intervention group than for the control group

Abbreviations: SA-I, state subdimension on the STAI; T-AI, STAI, trait subdimension on the STAI; Spielberger State-trait Anxiety Inventory.

responsibility and health knowledge scores reaching 41.36 ± 4.26, 28.18 ± 2.67, 21.19 ± 2.03, and 61.39 ± 6.14, respectively, with $P < .05$, and the control groups also increased significantly, with $P < .05$. However, the intervention group's increases were significantly greater than those of the control group, with $P < .05$.

Psychological State

The scores of the two groups for the state (Figure 4A) and trait (Figure 4B) subdimensions on the STAI weren't significantly different at baseline ($P > .05$). However, those scores decreased significantly in both groups postintervention ($P < .05$) and were significantly lower in the intervention group than in the control group ($P < .05$). This indicates that the psychological state of participants in both groups had been significantly improved postintervention, but the improvement effect was significantly greater for the intervention group than the control group.

DISCUSSION

In the current study, similar to Tschannen and Anderson's study,[28] no notable difference was found in clinical efficacy between the HFMEA-based predictive care combined with multimodal analgesia and routine nursing combined with multimodal analgesia for patients after OIFI, indicating the high safety and application value of the two measures.

Then the study compared the changes of RPN value between the two groups after surgery and found a significantly lower RPN value in the intervention group than that in the control group, denoting that HFMEA-based predictive care combined with multimodal analgesia could greatly reduce postoperative complications and could exert a positive impact on postoperative recovery and rehabilitation.

The comparison between the two groups of the results of the VAS related to analgesia in the current study showed that the intervention group had significantly lower VAS scores than the control group at each time point and also experienced lower self-controlled delivery of pain medication than the control group at each time point after surgery. Those results indicate that HFMEA-based predictive care combined with multimodal analgesia was more conducive to wound healing and patients' life quality.

Pitchon et al's study,[15] which found that analgesia technology is crucial for relieving patients' physical pain and improving therapeutic effects, supports the current study's results. Moreover, in the current study, the two groups weren't notably different in TNF-α and IL-6 levels at baseline, while postintervention, the levels in both groups were elevated, with significantly lower levels in the intervention group than those in the control group. The results imply that HFMEA-based predictive care combined with multimodal analgesia has positive effects in inhibiting the production of inflammatory mediators and relieving the inflammatory reaction.

The comparison of the incidence of postoperative adverse symptoms between the two groups in the current study indicated that the intervention group showed a significantly lower total incidence than the control group (3.45% vs 15.87%), which further supports the current study's results and reflects the application value of HFMEA-based predictive care combined with multimodal analgesia for OIFI.

In the current study, the intervention group expressed significantly higher satisfaction with the nursing than the control group did and also showed significantly higher self-care ability and a much better psychological state than the control group did. The results indicate that HFMEA-based predictive care combined with multimodal analgesia can lay a good foundation for the trauma recovery of patients undergoing OIFI because it effectively helps them to achieve an excellent rehabilitation state, with limb function being restored to normal as much as possible and life quality being better. The application value of this intervention means might also be reflected in the following aspects.

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However, without comparison of more types of nursing-service models, the current research team is still unable to come to the conclusion that HFMEA-based predictive care is the most suitable nursing-service model for patients undergoing OIFI. In addition, because of a limited number of participants in the current study, the statistical results might be incidental. Moreover, the follow-up in the current study was short, and a longer follow-up investigation is desirable to understand the long-term prognosis of the two groups. In view of the above limitations, the current research team will conduct more comprehensive experimental analyses to obtain more representative experimental results.

CONCLUSION

HFMEA-based predictive care combined with multimodal analgesia can substantially lower the risks and pain levels of patients undergoing OIFI and can improve their nursing experience and self-care ability, so it is worthy of clinical application, having great significance to patients' rehabilitation.

AUTHORS' DISCLOSURE STATEMENT

No conflict of interest.

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