

A RANDOMIZED CONTROLLED TRIAL TO EVALUATE THE EFFECTIVENESS OF A NURSING CARE PACKAGE ON SELECTED ADVERSE EFFECTS AMONG PATIENTS RECEIVING INJECTABLE ANTICOAGULANTS

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ABSTRACT

Background: Injectable anticoagulants are widely used in hospitalized patients for the prevention and treatment of thromboembolic disorders. Despite their effectiveness, these agents are associated with adverse effects such as pain and bruising at injection sites, which may affect patient comfort, adherence, and safety.

Objective: To evaluate the effectiveness of a structured Nursing Care Package (NCP) in reducing selected adverse effects—specifically pain and bruising—among hospitalized patients receiving subcutaneous injectable anticoagulants.

Methods: Randomized Controlled Trial study was conducted among 180 hospitalized patients receiving injectable anticoagulants, divided equally into experimental and control groups. The experimental group received a structured Nursing Care Package in addition to routine care, while the control group received routine care alone. Pain and bruise severity were assessed using standardized scales before and after the intervention. Data were analysed using descriptive and inferential statistics.

Results: Following the intervention, the experimental group demonstrated a significant reduction in mean pain scores (from 3.29 ± 1.81 to 1.89 ± 1.14 ; $p = 0.001$) and bruise scores (from 2.46 ± 0.89 to 1.77 ± 0.72 ; $p = 0.001$). Although the control group also showed some improvement, the magnitude of reduction was greater in the experimental group. No significant association was found between pain and selected co-morbidities ($\chi^2 = 7.504$, $p = 0.585$).

Conclusion: The Nursing Care Package was effective in significantly reducing pain and bruising associated with injectable anticoagulant therapy. Incorporating structured nursing interventions into routine care may improve patient outcomes and safety.

KEYWORDS: Nursing care package; injectable anticoagulants; pain; bruising; hospitalized patients.

INTRODUCTION

Injectable anticoagulants such as unfractionated heparin and low-molecular-weight heparin are routinely administered to hospitalized patients for the prevention and management of thromboembolic conditions. While these medications are clinically effective, they are commonly associated with local adverse effects including pain, bruising, and hematoma formation at injection sites. These complications, although often considered minor, can contribute to patient discomfort, anxiety, reduced adherence, and dissatisfaction with treatment (Hirsh et al., 2001).¹

Nurses play a pivotal role in administering injectable anticoagulants and monitoring patients for adverse effects. Evidence suggests that improper injection technique, inadequate site rotation, and insufficient patient education can increase the risk of local complications (Kesieme et al., 2011).² Structured nursing interventions focusing on education, correct technique, and monitoring may therefore reduce the occurrence and severity of these adverse effects.

Despite this, routine nursing care often lacks a standardized, comprehensive approach to managing injection-related complications. This gap highlights the need for structured Nursing Care Packages that systematically address patient education, skill reinforcement, and early identification of adverse effects. The present study was undertaken to evaluate the effectiveness of such a Nursing Care Package in reducing pain and bruising among hospitalized patients receiving injectable anticoagulants.³

MATERIALS AND METHODS

Study Design and Setting

A Randomized Controlled Trial design was adopted. The study was conducted in selected inpatient wards of a tertiary care hospital.

Study Population and Sample

The study included 180 hospitalized patients receiving subcutaneous injectable anticoagulants. Participants were allocated into:

- **Experimental group:** 90 patients who received the Nursing Care Package.

- **Control group:** 90 patients who received routine nursing care.

Intervention: Nursing Care Package

The Nursing Care Package consisted of:

- Education on anticoagulant therapy and adverse effects
- Demonstration and re-demonstration of correct injection technique
- Guidance on site rotation and skin preparation
- Monitoring for early signs of pain and bruising
- Reinforcement sessions during hospitalization

Data Collection Tools

Data were collected using a structured and standardized tool developed by the investigator. The tool consisted of three sections:

- **Section A:** Structured demographic and clinical proforma
- **Section B:** Numerical Pain Rating Scale (NPRS)
- **Section C:** Bruise Severity Scale

The Numerical Pain Rating Scale was used to assess the intensity of pain at the injection site, while the Bruise Severity Scale was used to evaluate the severity of bruising. The demographic and clinical proforma was used to obtain baseline information related to socio-demographic and health-related variables.

All assessments were conducted at two points: before the intervention (pre-test) and after the implementation of the Nursing Care Package (post-test) to determine the effectiveness of the intervention.

Statistical Analysis

Data were analysed using descriptive statistics (frequency, percentage, mean, standard deviation) and inferential statistics (paired t-test, chi-square test). A p-value < 0.05 was considered statistically significant.

Ethical Considerations

Ethical approval for the study was obtained from the Institutional Ethics Committee of **Parul University**, Vadodara, Gujarat. Written informed consent was obtained from all participants prior to data collection. Participants were informed about the purpose of the study, and confidentiality and anonymity were maintained throughout the research process. Participation was entirely voluntary, and participants were free to withdraw from the study at any time without any consequences.

3. RESULTS

3.1 Prevalence of Adverse Effects among Hospitalised Patients

Among the total of 720 hospitalized patients receiving subcutaneous injectable anticoagulants, 180 patients (25%) experienced one or more adverse effects, while 540 patients (75%) did not report any adverse effects. This finding indicates that approximately one in four patients developed treatment-related side effects, highlighting a clinically relevant prevalence of adverse outcomes associated with injectable anticoagulant therapy.

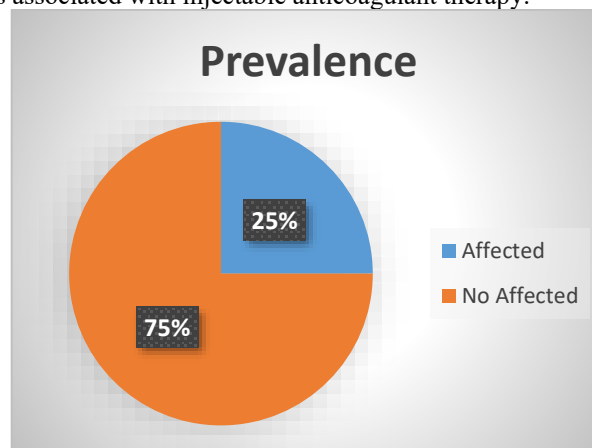


Figure-1 Prevalence Data

3.2 Baseline Demographic and Clinical Characteristics

A total of 180 patients were included in the interventional phase of the study, with 90 patients each in the experimental and control groups. The majority of participants in both groups belonged to the age group of 41–50 years, followed by 51–60 years. Male patients predominated in both groups.

Most participants were married, Hindu by religion, and had education up to high school or intermediate level. The occupational distribution of the head of the family was comparable between groups, with a majority engaged in skilled agricultural, clerical, or skilled labour occupations. Most participants belonged to a middle-income category.

Regarding clinical characteristics, a higher proportion of patients in the experimental group reported previous hospitalisation and previous surgery compared to the control group. However, the majority of participants in both groups had no co-morbid conditions. Diabetes mellitus and hypertension were the most commonly reported co-morbidities. Overall, the demographic and clinical variables were reasonably comparable between the experimental and control groups, indicating baseline homogeneity.

Table 1: Frequency and percentage distribution of demographic variable among patients who received nursing care package and who do not receive nursing care package

N=180

Demographic Variables	Categories	Experimental Group		Control Group	
		Frequency (f)	Percentage (%)	Frequency (f)	Percentage (%)
Age in Year	30 -40 Years	09	10	16	17.8
	41- 50 Years	32	35.6	38	42.2
	51- 60 Years	28	31.1	29	32.2
	Above 60 Years	21	23.3	07	7.8
Sex	Male	62	68.9	49	54.4
	Female	28	31.1	41	45.6
Religion	Hindu	65	72.2	55	61.1
	Muslim	18	20	28	31.1
	Christian	07	7.8	07	7.8
Marital status	Married	83	92.2	86	95.6
	Unmarried	00	00	00	00
	Divorced	00	00	00	00
	Widowed	07	7.8	04	4.4
Educational status	Profession or Honors	02	2.2	01	1.1
	Graduate Intermediate or diploma	24	26.7	27	30
	High school certificate	32	35.6	29	32.2
	Middle school certificate	19	21.1	19	21.1
	Primary school certificate	11	12.2	11	12.2
	Illiterate	02	2.2	03	3.3
Occupation of Head of the family	Legislators, Senior Officials & Managers	00	00	00	00
	Professionals	00	00	00	00
	Technicians and Associate Professionals	09	10	05	5.6
	Clerks	14	15.6	19	21.1
	Skilled Workers and Shop & Market Sales Workers	15	16.7	14	15.6
	Skilled Agricultural & Fishery Workers	23	25.6	24	26.7
	Craft & Related Trade Workers	08	8.9	12	13.3
	Plant & Machine	08	8.9	07	7.8

	Operators and Assemblers				
	Elementary Occupation	09	10	06	6.7
	Unemployed	04	4.4	03	3.3
Family income/ month (in Rupees)	≥184,376	03	3.3	02	2.2
	92,191-184,370	16	17.8	17	18.9
	68967-92185	35	38.9	35	38.9
	46095-68961	25	27.8	23	25.6
	27654-46089	10	11.1	11	12.2
	9232-27648	01	1.1	02	2.2
	≤9226	00	00	00	00
Previous hospitalization	Yes	63	70	28	31.1
	No	27	30	62	68.9
Previous surgery	Yes	32	35.6	12	13.3
	No	58	64.4	78	86.7
Co-morbidities	None	68	75.6	70	77.8
	Anemia	00	00	00	00
	Diabetes mellitus	15	16.7	13	14.4
	Hypertension	06	6.7	6	6.7
	Respiratory illness	01	1.1	01	1.1

3.3 Effect of Nursing Care Package on Pain

3.3.1 Distribution of Pain Levels

At pre-test, most patients in the experimental group reported mild to moderate pain, with 47.8% experiencing “hurts just a little bit” and 46.6% reporting moderate pain categories (“hurts a little more” or “hurts even more”). Only 5.6% of patients reported no pain.

Following the Nursing Care Package, a marked improvement was observed in the experimental group. At post-test, 77.8% of patients reported “hurts just a little bit” and 15.6% reported “very happy, no hurt”. Only 6.6% remained in moderate pain categories, indicating a substantial reduction in pain intensity.

In the control group, pre-test findings showed that 46.7% of patients experienced “hurts a little more” pain, while 41.1% reported “hurts just a little bit”. At post-test, although improvement was observed, with 83.3% reporting “hurts just a little bit” and 16.7% reporting no pain, the improvement appeared less attributable to a structured intervention and more likely related to routine care and natural recovery.

3.3.2 Comparison of Mean Pain Scores

The mean pre-test pain score in the experimental group was 3.29 ± 1.81 , which reduced significantly to 1.89 ± 1.14 at post-test. The reduction was statistically significant ($t = 0.001$, $p < 0.05$), indicating the effectiveness of the Nursing Care Package in reducing pain.

In the control group, the mean pain score decreased from 3.42 ± 1.35 at pre-test to 1.67 ± 0.75 at post-test, and this reduction was also statistically significant ($p = 0.002$). However, the greater reduction in the experimental group suggests an added benefit of the structured nursing intervention beyond routine care.

3.4 Effect of Nursing Care Package on Bruising

3.4.1 Distribution of Bruise Severity

At baseline, a high proportion of patients in the experimental group exhibited moderate to severe bruising. Severe bruising was observed in 43.3% of patients, while 34.4% had moderate bruising. Extreme severe bruising was present in 8.9% of patients.

Following the Nursing Care Package, a substantial improvement was observed. Severe bruising decreased to 12.2%, and extreme severe bruising was completely eliminated. The proportion of patients with mild and moderate bruising increased, reflecting a shift towards lower severity categories.

In the control group, moderate bruising remained predominant both at pre-test (47.8%) and post-test (68.9%). Although severe and extreme severe bruising decreased at post-test, the overall reduction in severity was less pronounced compared to the experimental group.

3.4.2 Comparison of Mean Bruise Scores

The mean pre-test bruise score in the experimental group was 2.46 ± 0.89 , which significantly reduced to 1.77 ± 0.72 at post-test ($p = 0.001$). This indicates that the Nursing Care Package was effective in reducing both the occurrence and severity of bruising.

In the control group, the mean bruise score decreased marginally from 2.27 ± 0.79 to 2.00 ± 0.56 at post-test. Although statistically significant, the reduction was smaller compared to the experimental group, highlighting the superior effectiveness of the structured nursing intervention.

3.5 Association between Pain and Co-morbid Conditions

The association between pain levels and selected co-morbid conditions was analysed using the chi-square test. The analysis revealed no statistically significant association between pain and co-morbidities such as diabetes mellitus, hypertension, or respiratory illness ($\chi^2 = 7.504$, $df = 9$, $p = 0.585$). This indicates that pain levels were independent of the presence of co-morbid conditions and that the observed reduction in pain was primarily attributable to the nursing intervention.

DISCUSSION

The present study evaluated the effectiveness of a structured Nursing Care Package (NCP) in reducing selected adverse effects among hospitalised patients receiving subcutaneous injectable anticoagulants. The findings demonstrate that patients who received the Nursing Care Package experienced a significantly greater reduction in pain and bruising compared to those who received routine nursing care alone.

In the current study, a considerable proportion of patients reported pain and bruising at baseline, which is consistent with existing literature indicating that local adverse effects are common complications of injectable anticoagulant therapy. These adverse effects are often related to improper injection techniques, inadequate site rotation, insufficient skin preparation, and lack of patient awareness regarding preventive measures. The significant improvement observed in the experimental group suggests that targeted nursing interventions addressing these factors can effectively mitigate such complications.

The marked reduction in pain intensity following the Nursing Care Package may be attributed to improved injection techniques, appropriate needle handling, proper site selection, and enhanced patient education. Similar findings have been reported in earlier studies, where structured education and nursing-led interventions were associated with improved patient comfort and reduced injection-related pain. Education and reinforcement likely reduced anxiety related to injections, which may have further contributed to lower perceived pain levels.

With regard to bruising, the experimental group demonstrated a substantial decline in the severity of bruises, including complete elimination of extreme severe bruising at post-test. This finding underscores the importance of correct injection angle, avoidance of vigorous massage, adequate compression at the injection site, and regular site rotation—key components of the Nursing Care Package. In contrast, the control group showed only modest improvement, suggesting that routine care alone may be insufficient to prevent or minimise bruising.

The absence of a significant association between pain levels and selected co-morbid conditions indicates that the effectiveness of the Nursing Care Package was consistent across different patient subgroups. This finding strengthens the general applicability of the intervention and suggests that structured nursing care can benefit a wide range of patients receiving injectable anticoagulants, irrespective of underlying co-morbidities.

Overall, the findings highlight the critical role of nurses in preventing treatment-related complications and improving patient outcomes through structured, evidence-based care approaches.

CONCLUSION

The study concludes that the structured Nursing Care Package was effective in significantly reducing pain and bruising among hospitalised patients receiving subcutaneous injectable anticoagulants. Patients who received the intervention demonstrated greater improvement in adverse effect outcomes compared to those receiving routine nursing care alone.

These findings emphasise the importance of incorporating structured nursing interventions, including patient education, correct injection techniques, and systematic monitoring, into routine clinical practice. Implementation of such Nursing Care Packages may enhance patient comfort, promote safety, and improve the overall quality of anticoagulant therapy.

Implications for Nursing Practice

The findings of this study highlight the importance of structured nursing interventions in reducing injection-related adverse effects among patients receiving anticoagulant therapy. Implementation of a standardized Nursing Care Package can enhance nursing competency, improve patient comfort, and reduce preventable complications. Incorporating such packages into routine hospital protocols may strengthen patient safety practices and improve the overall quality of nursing care.

Limitations of the Study

The study was conducted in a single tertiary care hospital, which may limit the generalisability of the findings. The follow-up period was relatively short and focused primarily on immediate adverse effects. Future studies with multi-centre designs and longer follow-up durations are recommended to further validate the effectiveness of the Nursing Care Package.

Recommendations

Future studies should examine the effectiveness of structured Nursing Care Packages on a broader range of outcomes, including bleeding complications, anxiety related to anticoagulant administration, and long-term adherence to therapy. Multi-centre studies with extended follow-up periods are recommended to strengthen the evidence base and enhance

generalisability. In addition, structured training programmes for nurses based on standardised care packages should be developed and integrated into routine clinical practice to promote uniformity, sustainability, and adherence to best nursing practices.

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Conflict of interest

The authors declare that there is no conflict of interest associated with this study.

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