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Research Proposal on :

Prevalence of Intra-Dialytic Complications and Associated Risk Factors Among Patients on Maintenance Hemodialysis in Dongola City, Sudan, 2026.

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1. INTRODUCTION

1.1. Background

Intradialytic complications are adverse clinical events that occur during a hemodialysis session, ranging from mild symptoms to potentially life-threatening events, and that may require intervention or modification of the dialysis treatment (1). They include intradialytic hypotension, intradialytic hypertension, muscle cramps, nausea and vomiting, headache, chest pain, chills and rigors, and dizziness (1).

Global Evidence

In Nepal, 58.3% of 228 patients experienced at least one intradialytic complication, mainly chills and rigor (44.3%), backache (30.7%), and hypotension (27.2%) (2). In India, complications were reported in 12.24% of 245 patients (3), while in Central Nepal they were reported in 61.5% of 143 patients, with intradialytic hypertension (39.9%) being the most common (4).

Regional Evidence

In Africa, intradialytic hypotension was reported in 7.4% of 2,111 hemodialysis sessions among 215 patients in Tanzania, where abnormal pre-dialysis vital signs and blood flow rate were associated with it (5), and in 13.4% of 186 patients in Uganda, where heart failure, diabetes, and severe anemia were associated with it (6).

Evidence from Sudan

In Sudan, a descriptive hospital-based study among 105 patients receiving hemodialysis at Kassala Dialysis Center reported joint pain (53.3%), sleeping disturbances (32.4%), and muscle cramps (31.4%) as commonly reported adverse effects of hemodialysis (7).
A conference abstract from a tertiary hemodialysis center in Khartoum reported a cross-sectional study in which the prevalence of intradialytic hypertension was 29% (26/89; 95% CI: 20–39%) among patients receiving maintenance hemodialysis, with central venous catheter use significantly associated with it (8).
However, evidence on the prevalence and associated factors of intradialytic complications among patients receiving maintenance hemodialysis in Sudan remains limited.

1.2. Problem Statement

Intradialytic complications are reported among patients receiving maintenance hemodialysis in different settings, with studies in Nepal reporting complications in 58.3% and 61.5% of patients (2,4), intradialytic hypotension in 7.4% of dialysis sessions in Tanzania and 13.4% of patients in Uganda (5,6), and a study at Kassala Dialysis Center in Sudan reporting joint pain in 53.3%, sleep disturbances in 32.4%, and muscle cramps in 31.4% of patients (7).

These complications, particularly intradialytic hypotension, can have important clinical consequences, including increased mortality, cardiovascular morbidity, vascular access thrombosis, and considerable patient distress during dialysis (9–12), making it important to determine their prevalence and associated risk factors; however, to our knowledge, no study has assessed these complications among maintenance hemodialysis patients in Dongola City, and therefore their prevalence and associated factors in this population remain unknown.

1.3. Justification

Dongola is the capital of Northern State, Sudan, with a population of 56,167 according to the 2008 census (14). El Gomaih Dialysis Center is an important healthcare facility in Dongola, providing hemodialysis services to patients with end-stage renal disease. A study using data from September 2025 reported that the center served 312 patients (15).

Patients receiving maintenance hemodialysis are at risk of intradialytic complications, including hypotension, hypertension, and muscle cramps, which may interrupt treatment and adversely affect patient safety and outcomes (9,13).

To our knowledge, evidence on the prevalence and associated factors of intradialytic complications among maintenance hemodialysis patients in Dongola City is limited. This study can provide local baseline data, help identify patients at higher risk, support appropriate monitoring and early management, and serve as a basis for future research and quality improvement in Dongola and other parts of Sudan.

1.4. Research Questions

1. What is the prevalence of intradialytic complications among patients on maintenance hemodialysis at El Gomaih Dialysis Center, Dongola City?

2. What are the most common intradialytic complications (hypotension, hypertension, muscle cramps, nausea/vomiting, headache, chest pain, chills and rigors, dizziness)?

3. Which demographic, clinical, and dialysis-related factors are associated with the occurrence of intradialytic complications?

4. Is there an association between comorbidities (diabetes mellitus, hypertension, cardiovascular disease) and the occurrence of intradialytic complications?

1.5. Hypothesis

Null hypothesis (H_0): There is no significant statistical association between the occurrence of intradialytic complications and any of the following factors: age, sex, diabetes mellitus, hypertension, cardiovascular disease, anemia, use of antihypertensive medication before dialysis, duration on hemodialysis, type of vascular access, interdialytic weight gain, ultrafiltration volume, pre-dialysis blood pressure, or regularity of attendance, among patients on maintenance hemodialysis at El Gomaih Dialysis Center, Dongola City.

Alternative hypothesis (H_1): There is a significant association between the occurrence of intradialytic complications and at least one of the following factors: age, sex, diabetes mellitus, hypertension, cardiovascular disease, anemia, use of antihypertensive medication before dialysis, duration on hemodialysis, type of vascular access, interdialytic weight gain, ultrafiltration volume, pre-dialysis blood pressure, or regularity of attendance, among patients on maintenance hemodialysis at El Gomaih Dialysis Center, Dongola City.

1.6. Objectives

1.6.1. General Objective

To evaluate the prevalence of intradialytic complications and their associated factors among patients on maintenance hemodialysis at El Gomaih Dialysis Center, Dongola City.

1.6.2. Specific Objectives

1. Estimate the prevalence of intradialytic complications among patients on maintenance hemodialysis at El Gomaih Dialysis Center, Dongola City.

2. To identify the most common intradialytic complications among patients on maintenance hemodialysis at El Gomaih Dialysis Center, Dongola City.

3. To determine the demographic, clinical, and dialysis-related factors associated with the occurrence of intradialytic complications among patients on maintenance hemodialysis at El Gomaih Dialysis Center, Dongola City.

4. To determine the association between comorbidities, including diabetes mellitus, hypertension, and cardiovascular disease, and the occurrence of intradialytic complications among patients on maintenance hemodialysis at El Gomaih Dialysis Center, Dongola City.

2. LITERATURE REVIEW

2.1. Global Evidence

Bartaula et al. studied 228 patients receiving maintenance hemodialysis in Nepal and found that 58.3% experienced at least one intradialytic complication. Chills and rigor (44.3%), backache (30.7%), and hypotension (27.2%) were commonly reported. Increasing age and irregular hemodialysis were significantly associated with complications (2).

Jagadeesan and Vijayakumar conducted a prospective study among 245 patients in India and reported intradialytic complications in 12.24%. Hypertension, hypotension, vomiting, headache, and shortness of breath were reported complications (3).

Sharma et al. studied 143 patients in Central Nepal and reported intradialytic complications in 61.5%. Intradialytic hypertension (39.9%), hypotension (14.7%), and headache (14.7%) were reported. Diabetes, hypertension, dialysis duration, and food consumption were examined as associated factors (4).

Sah et al. studied 72 patients in Nepal and reported that all participants experienced at least one intradialytic complication. Nausea and vomiting (81.9%) and chills and rigor (79.2%) were commonly reported (16).

Narayanaswamy et al. studied 70 patients in Karnataka, India, and reported that all participants experienced at least one complication, while 84.3% experienced multiple complications. Muscle cramps (75.7%), chills (47.1%), itching (38.5%), and hypotension (34.3%) were reported (17).

Ali et al. studied 94 patients in Pakistan and reported hypotension in 28.7%, hypertension in 17.0%, and nausea or vomiting in 11.7% (18).

Ray et al. studied 197 patients in Bangladesh and reported intradialytic hypotension in 49.7% and muscle cramps in 37.6%. Diabetes was significantly associated with intradialytic hypotension (19).

2.2. Regional Evidence

Dugilo et al. studied 215 patients (2,111 hemodialysis sessions) in Tanzania and reported intradialytic complications in 36.6% of sessions, including intradialytic hypertension (26.5%) and hypotension (7.4%). Abnormal pre-dialysis vital signs and blood flow rate were significantly associated with both hypertension and hypotension, while male sex was protective against hypotension (5).

Nkoyooyo et al. studied 186 patients in Uganda and reported intradialytic hypotension in 13.4%. Heart failure, diabetes, and severe anemia were significantly associated with intradialytic hypotension (6).

Mohamed et al. studied 149 patients in Somalia and reported intradialytic hypotension in 55.0% and intradialytic hypertension in 12.1%. Higher pre-dialysis systolic blood pressure and a higher ultrafiltration goal were significantly associated with hypotension (20).

2.3. Sudan

In Sudan, Ahmed et al. conducted a descriptive hospital-based study among 105 patients receiving hemodialysis at Kassala Dialysis Center and reported joint pain (53.3%), sleeping disturbances (32.4%), and muscle cramps (31.4%) as commonly reported adverse effects of hemodialysis (7).

Khogalee et al. reported, in a conference abstract, a cross-sectional study conducted at a tertiary hemodialysis center in Khartoum, Sudan, in which the prevalence of intradialytic hypertension was 29% (26/89; 95% CI: 20–39%) among patients receiving maintenance hemodialysis. Central venous catheter use was significantly associated with intradialytic hypertension (8).

2.4. Summary of Literature Review

The reported prevalence of intradialytic complications varies widely across studies, from 12.2% of 245 patients in India (3) to 100% of 72 patients in Nepal (16) and 70 patients in Karnataka, India (17). Studies that reported an overall prevalence found it in 58.3% and 61.5% of patients in Nepal (2,4), and in 36.6% of 2,111 sessions among 215 patients in Tanzania (5). Hypotension was the most frequently reported specific complication, ranging from 7.4% of sessions in Tanzania (5) to 55.0% of patients in Somalia (20), with 28.7% in Pakistan (18) and 49.7% in Bangladesh (19). Intradialytic hypertension, muscle cramps,

nausea/vomiting, chills, and headache were also commonly reported (2–4,16–19).

Several factors were associated with these complications, including diabetes, heart failure, severe anemia, abnormal pre-dialysis vital signs, higher pre-dialysis systolic blood pressure, and a higher ultrafiltration goal (5,6,19,20).

In Sudan, evidence remains limited. A study in Kassala reported joint pain (53.3%), sleep disturbances (32.4%), and muscle cramps (31.4%) (7), while a conference abstract from Khartoum reported intradialytic hypertension in 29% of patients, with central venous catheter use significantly associated with it (8). No study has addressed this in Dongola City.

3. METHODOLOGY

3.1. Study Design

An analytical cross-sectional study.

3.2. Study Setting

The study will be conducted at El Gomaih Dialysis Center, Dongola City, Northern State, Sudan.

3.3. Study Period

The study will be conducted from 4 October 2026 to 19 November 2026, covering data collection, data analysis, and preparation and submission of the final research report.

3.4. Study Population

The study population will consist of adult patients (≥18 years) receiving maintenance hemodialysis at El Gomaih Dialysis Center during the study period.

Inclusion criteria:

- Adult patients (≥18 years).

- Patients receiving maintenance hemodialysis for ≥3 months.

Exclusion criteria:

- Patients who are critically ill and unable to participate in data collection.

- Patients unwilling to participate.

3.5. Sample Size Calculation

The sample size will be calculated using the following formula for a single population proportion with a finite population:

$$n = N \times Z^2 \times p \times q / [d^2 \times (N - 1) + Z^2 \times p \times q]$$

Where:

- n = required sample size
- N = total study population = 324
- Z = 1.96 at 95% confidence level
- p = 0.50, as the prevalence is unknown
- q = 1 − p = 0.50
- d = 0.05 margin of error

Substitution:

$n = 324 \times (1.96)^2 \times (0.50) \times (0.50) / [(0.05)^2 \times (324 - 1) + (1.96)^2 \times (0.50) \times (0.50)]$

$n = 324 \times 3.8416 \times 0.25 / [0.0025 \times 323 + 3.8416 \times 0.25] = 311.17 / 1.7679 = 176.01$

n = 177 patients (rounded up)

With the addition of a 5% non-response rate:

Adjusted $n = 177 / (1 - 0.05) = 186.3$, rounded up to 187 patients

Therefore, the final sample size will be 187 patients.

3.6. Sampling Technique

Consecutive sampling will be used. Eligible maintenance hemodialysis patients attending El Gomaih Dialysis Center on the selected data-collection days will be recruited consecutively until the required sample size of 187 patients is reached. The medical record number will be checked before data collection to avoid duplicate participation, and each patient will be included only once during the study period. Data-collection days will be selected in coordination with the center administration to cover all weekly dialysis schedules, so that all eligible patients have a chance of being included.

3.7. Data Collection

Data will be collected on specific days determined by the center administration from eligible maintenance hemodialysis patients attending El Gomaih Dialysis Center. A structured questionnaire will be developed and administered using **KoboToolbox**. Eligible patients will be recruited consecutively and interviewed after verbal informed consent has been obtained. Relevant clinical and dialysis-related data will be obtained from the patients' medical records and recorded in the KoboToolbox form. The medical record number will be checked before data collection to ensure that each patient is included only once.

3.8. Study Variables

Dependent variable:

- Patient-level occurrence of intradialytic complications (categorized as Yes if ≥1 complication occurred across the last 6 sessions, and No if no complications occurred).

Independent variables:

Demographic:

- Age.

- Sex.

Clinical:

- Diabetes mellitus.

- Hypertension.

- Cardiovascular disease.

- Anemia.

- Use of antihypertensive medication before dialysis.

Dialysis-related:

- Duration on hemodialysis.

- Type of vascular access.

- Interdialytic weight gain (mean of the last six sessions).

- Ultrafiltration volume (mean of the last six sessions).

- Pre-dialysis blood pressure (mean of the last six sessions).

- Regularity of attendance.

3.9. Operational Definitions

Maintenance hemodialysis: Regular hemodialysis treatment (usually three sessions per week) received for at least 3 months before the date of data collection (21).

Intradialytic complication: Occurrence of at least one of the following during the last six hemodialysis sessions before data collection, as documented in the patient's medical record or reported by the patient: hypotension, muscle cramps, nausea/vomiting, headache, chest pain, chills and rigors, or dizziness in at least one session, or intradialytic hypertension as defined below (1).

Intradialytic hypotension: A decrease in systolic blood pressure ≥20 mmHg or in mean arterial pressure ≥10 mmHg during a session, associated with symptoms or requiring intervention (1,22).

Intradialytic hypertension: An increase in systolic blood pressure of more than 10 mmHg from pre-dialysis to post-dialysis, with post-dialysis blood pressure within the hypertensive range, in at least 4 of the last 6 consecutive hemodialysis sessions (21,23).

Muscle cramps: Painful, involuntary muscle contractions occurring during a session, reported by the patient or recorded in the dialysis notes (24).

Nausea/vomiting, headache, chest pain, chills and rigors, dizziness: New onset of the symptom during a session, reported by the patient or recorded in the dialysis notes (1).

Anemia: Hemoglobin < 13 g/dL in men and < 12 g/dL in women (25).

Interdialytic weight gain: Pre-dialysis weight (kg) minus the post-dialysis weight (kg) of the previous session, calculated as the mean of the last six sessions (26).

Type of vascular access: Arteriovenous fistula, arteriovenous graft, or central venous catheter, as recorded in the patient’s medical record (27).

Regularity of attendance: Regular if the patient did not miss any scheduled hemodialysis session completely during the month before data collection; irregular if one or more sessions were missed (28).

3.10. Data Management and Statistical Analysis

Data collected through KoboToolbox will be exported to Excel and analyzed using SPSS version 26. Categorical variables will be summarized as frequencies and percentages, and continuous variables as means ± standard deviation or medians with interquartile ranges, as

appropriate. The prevalence of intradialytic complications will be reported with its 95% confidence interval. Comparative and multivariable analyses will be conducted at the patient level (N = 187), while session-level frequencies (N = 1,122 sessions) will be reported for descriptive purposes only. Associations with categorical variables will be assessed using the Chi-square test (or Fisher's exact test when its assumptions are not met), and continuous variables will be compared between patients with and without complications using the independent t-test or the Mann–Whitney U test, as appropriate. Variables with a p-value <0.20 in the bivariate analysis will be entered into a binary logistic regression model, with the number of variables limited according to the number of events, and crude and adjusted odds ratios with 95% confidence intervals will be reported. Model fit will be assessed using the Hosmer–Lemeshow test, and multicollinearity will be checked before model building. A p-value <0.05 will be considered statistically significant.

3.11. Ethical Considerations

Ethical approval will be obtained from the Ministry of Health, Northern State, through the University of Dongola, and administrative permission will be obtained from the administration of El Gomaih Dialysis Center. Verbal informed consent will be obtained from all participants after explaining the purpose, procedures, risks, and benefits of the study. Participation will be entirely voluntary, and patients will retain the right to withdraw at any time without affecting their ongoing dialysis care. Confidentiality will be strictly maintained: data gathered via KoboToolbox will be stored on password-protected cloud servers and local devices using unique identification codes instead of patient names.

3.12. Research Plan

The study will proceed through the following stages: (1) finalization and departmental approval of the proposal; (2) securing ethical approval from the Ministry of Health, Northern State, through the University of Dongola, and administrative permission from El Gomaih Dialysis Center; (3) pretesting the KoboCollect questionnaire and record-abstraction checklist on a small number of patients outside the study sample, with tool refinement as needed; (4) recruitment of eligible patients and collection of informed consent; (5) data collection through structured interviews and medical record abstraction; (6) data cleaning, coding, and entry verification; (7) statistical analysis in SPSS; (8) writing of results, discussion, and the final report; and (9) presentation of findings at the departmental research seminar and defense.

4. TIMELINE


TIMELINE FOR GRADUATION RESEARCH
PHASE / TASK
SEPTEMBER
OCTOBER
NOVEMBER
DECEMBER
JANUARY
W1
W2
W3
W4
W5
W6
W7
W8
W9
W10
W11
W12
W13
W14
W15
W16
Submission of Research Proposals
Sep 20–24, 2026
Presentation of Research Proposals
Sep 27 – Oct 1, 2026
Data Collection
Oct 4–22, 2026
Data Analysis
Oct 25 – Nov 5, 2026
Writing Results and Discussion
Nov 8–19, 2026
Writing the Final Report
Nov 22 – Dec 3, 2026
Electronic Submission to the Department of Community Medicine
Dec 6–10, 2026
Research Evaluation (Peer Review)
Dec 13–24, 2026
Revisions to Research
Dec 27–31, 2026
Research Defense (Discussion)
Jan 3–4, 2027

RESEARCH PROJECT BUDGET

#	Item Description	Quantity	Unit Cost (SDG)	Total Cost (SDG)
1	Mobile Data & Cloud Storage (Kobo Toolbox setup)	Lump sum	—	30,000
2	Transportation (Field visits to El Gomaih Dialysis Center)	30 trips	5,000	150,000
3	Data Analysis (SPSS processing & export)	Lump sum	—	300,000
4	Miscellaneous / Contingency	Lump sum	—	70,000
	Total Estimated Budget			**550,000 SDG**

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