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Pediatric Emergency Cases Managed with Intraosseous Access: Indications, Complication and Outcomes

Thesis

of Dissertation for the Academic Degree of PhD in Medicine

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General description of the study

Relevance of the problem

When peripheral venous catheterization is problematic or impossible, an alternative method for delivering fluids and drugs, as well as for obtaining samples for clinical laboratory testing, is the intraosseous technique. The intraosseous technique was initially applied in 1922, and it was most widely employed in the 1940s when patients who had suffered severe injuries during World War II frequently needed immediate medical attention.

The intraosseous technique has been obsolete since the 1950s with the advent of peripheral venous catheters (3). Peripheral venous catheterization is not always the best option for managing pediatric emergencies, though, as was discovered in the 1980s. Peripheral vein catheterization may take a long time or cannot be performed due to anatomical and physiological features, such as excessive subcutaneous fat tissue, small caliber veins. Because of vasoconstriction, decreased circulating blood volume, and peripheral venous collapse, peripheral venous catheterization is also difficult or impossible in cases of cardiopulmonary arrest, septic or hypovolemic shock, and prolonged status epilepticus.

It was necessary to locate an alternative way. According to studies, the only other quick, efficient, and low-complication method for giving children fluids and drugs is the intraosseous technique.

Due to the importance of the issue, the American Heart Association (AHA) and the American Academy of Pediatrics (AAP) have included a chapter on resuscitation of the pediatric and neonatal contingent in the Advanced Cardiac Life Support (ACLS) manual, where the intraosseous approach is considered as the only alternative for the delivery of fluids and drugs. way. The 2009 update to the American College of Critical Care Medicine's sepsis guideline included consideration of the intraosseous method as a substitute for maintaining hemodynamic stability in infants and young children. According to certain studies, the success rate of intraosseous injection is over 90%, which is a significant clinical signal. Furthermore, if a skilled professional and outstanding medical equipment are used, an intraosseous injection can be completed in less than two minutes.

Aim of the study

To study the indications of intraosseous approach in the management of emergency situations in children, the impact on the outcome of emergency care, the complications of intraosseous approach and its risk factors.

Research Objectives

Objective 1. Intraosseous method implementation in Georgia's pediatric emergency rooms

Objective 2. An assessment of infection control strategies in pediatric emergency rooms

Objective 3. An assessment of the effect of intraosseous access on emergency patients' first 24-hour mortality

Objective 4. Examining how intraosseous emergency care affects patient delays in the critical care unit

Objective 5. Study of intraosseous approach complications and its risk factors

Objective 6. Clearly defining the indications for an intraosseous approach in the pediatric emergency.

The work's scientific originality

As of right now, Georgia's pediatric population does not receive emergency care via the intraosseous method. While the intraosseous approach presents a viable option for handling pediatric emergencies, there is a lack of global data regarding the effects of this approach on emergency outcomes, and the indications for its use in pediatric emergency management remain unclear.

The findings of the study that was done enable us to:

- To specify precisely the indications for the intraosseous approach in the management of emergency cases in children;
- To evaluate how the intraosseous technique affects hospital delays and emergency mortality
- To determine the type, frequency and risk factors of intraosseous approach complications in children.

The results will be shared through reports at scientific conferences, publications in scientific journals, and training sessions offered by professional associations.

Approbation of the work

The test date for the paper was January 24, 2024 in M.Iashvili Children's Central Hospital's conference room.

Dissertation materials and results were reported:

1. Intraosseous Infusion Approach Management of Pediatric Emergencies: Indications, Effect on Outcome, and Complications

The substance of the dissertation work and its findings are adequately reflected in the reports and publications published in relation to the research.

Structure and sections of the dissertation

The dissertation consists of 8 parts: the introduction, literature review, material and methods, research results, conclusions, suggestions, and list of cited works.

The 54 pages of the work are illustrated with one diagram and seven tables.

There are 99 sources in the literature.

Design and methodology of the research

The data were statistically processed using the SPSS methodology, and a quasi-experimental cohort study was conducted. The study comprised children who were admitted to the pediatric emergency medical care departments of four children's clinics located in various regions of Georgia in 2018–2019, ranging in age from 1 to 15.

The research design and procedure were defined as follows:

The study comprised patients who were admitted with emergency conditions (see below) that necessitated the rapid administration of drugs and

infusion solutions. The Pediatric Early Warning Score was utilized to assess the severity of the patients. The trial was designed in a non-randomized fashion, with intraosseous catheterization performed on all patients who were unable to have a peripheral vein put into them within two minutes of the manipulation starting. Since there were two study groups, the groups (venous vs. intraosseous catheterization groups) were compared in terms of clinical results.

Research inclusion and exclusion criteria

The criteria for inclusion in the intraosseous catheterization group were defined as:

Emergencies in which it is difficult or impossible to catheterize a peripheral vein:

- Conditions in which significant amounts of fluid must be transfused quickly in cases of hypovolemia, cardiogenic shock, distributive shock, or obstructive shock
- Conditions needing systemic venous circulation access because of burns, cardiac arrest, or cardiorespiratory arrest

The following were listed as contraindications to intraosseous catheterization:

- Patients with:
 - o Intracardiac shunt
 - Oncological diseases
 - Immunosuppression
 - Bone structure pathology

- Osteogenesis imperfecta
- Osteoporosis
- Osteopetrosis
- Fracture at the site of the intraosseous approach
- Bone defect due to previously performed intraosseous approach
- Limitation of blood supply to the limb at the site of the intraosseous approach
- Presence of cellulitis, burns, or osteomyelitis at the site of the intraosseous approach

Methods

- As mentioned above, the study was conducted in four children's clinics of Georgia: M.Iashvili Children's Central Hospital (Clinic #1), Batumi Maternal and Child Central Hospital (Clinic #2), Tbilisi "Amtel" Hospital (Clinic #3) and Tbilisi Children's Infectious Clinical Hospital (Clinic #4). Of these, intraosseous catheterization training was conducted in two clinics (M.Iashvili Children's Central Hospital, Batumi Maternal and Child Central Hospital) and not in the other two clinics. Clinics were selected according to the following principle: multi-professionalism and experience of serving patients of similar profile and severity.
- In the hospitals that were part in the study, patient demographic (age, gender) and medical (diagnosis at admission, degree of severity, results of laboratory and instrumental tests, performed interventions,

and outcome) data were gathered. As per the protocol, bacteriological culture was performed as soon as possible to verify the sterility of the medical equipment following insertion and removal of the intraosseous approach-corresponding devices in all patients in which an alternate method was employed.

- Patients were not randomly assigned to study groups; instead, the corresponding group consisted of all patients (26 in total) who did not catheterize the peripheral vein within 1-2 minutes of the manipulation beginning and for which an intraosseous catheter was inserted. The remaining patients were combined with IV in the catheterization group.
- The overall study population's rate of death during the first 24 hours was assessed; data were also contrasted between patient groups receiving intraosseous treatment and those receiving IV catheterization.
- The pre- and post-test results were used to assess the knowledge and abilities that the relevant clinic personnel had received in their training to perform intraosseous catheterization. The outcomes of repeated testing were compared with the short-term results in order to assess the long-term (1 year after the training) results of the training.

Study Findings

140 patients' data from all four clinics were examined in study groups; 114 individuals were assigned to a different group, and 26 patients received training in intraosseous catheterization (the insertion of an intraosseous catheter); Note that the patients from clinic #1 were part of the intraosseous catheterization group; in other cases, this procedure was not used during the study period, and the group was designated as the IV catheterization or comparison group (see Table #3).

	0	1	2	3
Behaviour	Playing/ Adequate to the situation	Sleeping	Irritated	Slowed reaction to pain or lethargic/confused
Cardiovascular	Pink or capillary refill time 1-2 s.	Pale or pinkish or capillary refill time 3 s.	Tachycardia, compared to the norm, increased by 20 or gray or cyanotic or cap. Filling time is 4 seconds.	Tachycardia more than 30 beats normal or bradycardia or Gray or cyanotic and dewy or capillary refill time ≥ 5 s.
Respiration	within the norm	30+% FiO2 or 3 + l/min or 10 above normal or accessory muscle involvement	40+% FiO2 or 6 + L/min or retractions or increased by 20 over normal parameters	50 +% FiO2 or 8 + l/min or less than 5 times normal parameters or marked retraction or hollow tone

Table # 1. Pediatric early warning signs

Note: mild patient = 0-2 points; Moderate patient = 3 points; Severe patient = 4 points

Critically ill patient = 5 or more points

The study's findings, using four clinics as an example, demonstrated the unique clinical care of the study participants' patients.

The "Pediatric Early Danger Signs" collected at all study clinics were used to assess the severity of the patients included in the study (see Table #1).

Table #2 indicates that the severity of patients "caught" in Clinic #1's intraosseous catheterization group is similar to other clinics' patient groups' condition.

 Table # 2. Comparison of patient groups of hospitals included in the study according to severity

Severity	Clinic #1	Clinic #2	Clinic #3	Clinic #4
Critically ill	26	21	33	40
Severe patient		9		
Moderate patient		2	1	
Mild patient		8		

The benefits of applying the IO approach to critically ill patients are outlined in Table #3. The table shows that, of the 26 patients, only 9 (or 35%) required to continue treatment in the intensive care unit, and that 65 percent of patients continued their care in other somatic departments, with 100 and 97 patients receiving care in Clinics #2, #3, and #4, respectively. Additionally, all patients (100%) are still receiving care in the intensive care unit. Another noteworthy statistic is that 67% of patients at clinic #1 remain in the intensive care unit for more than 24 hours, while the corresponding percentages for clinics #2, #3, and 4 are 42.5%, 96%, and 80%.

As was previously noted, the study included 140 hospitalization-related cases with pertinent diagnoses or conditions from 4 clinical bases. 18 patients (13%), who needed to be transferred from the emergency room to a somatic unit for additional treatment, were among the 122 patients (87%) who needed to be moved from the emergency room to the intensive care unit; 28 (20%) patients needed to be in critical care for less than 24 hours, while 87 (62%) patients needed to be in intensive care for more than 24 hours; 2 (1%) patients died within the first 24 hours;

When applying the intraosseous technique, no patient experienced difficulties in the form of a local infection; however, 8 (6%) patients needed to be referred to another hospital.

If patients of varying severities were traditionally combined in the groups, the question of whether groups IO and IV are comparable in terms of clinical management and outcome might be contested. In particular, all patients in the first (intraosseous catheterization) group are no less serious from the point of view of clinical diagnosis than those in the IV group (see table #2).

Table #3. Clinical management characteristics and study-enrolled patient outcomes, both in the intraosseous technique group and out of it.

	The outcome of patients' condition after IO catheterization	Clinic #1	Clinic #2	Clinic #3	Clinic #4	Patients without IO	Total number of patients.
1	Total number of patients.	26	40	34	40	114	140
2	Degree of hospitalization	100%	100%	100%	100%	100%	100%
3	Transfer from emergency to ICU	9 (35%)	40 (100%)	33 (97%)	40 (100%)	113 (99%)	122 (87%)
4	After stabilizing the condition in the emergency room, transfer to the department	17 (65%)	0	1 (3 %)	0	1 (0.8%)	18 (13 %)
5	Length of ICU stay < 24 hours	3 (33 %)	15 (37.5 %)	2 (6%)	8 (20%)	25 (21%)	28 (20%)
6	Length of ICU stay > 24 hours	6 (67 %)	17 (42.5%)	32 (96%)	32 (80%)	81 (71%)	87 (62%)
7	Solution within 24 hours (death in first 24 hours)	0	2 (5%)	0	0	2 (0.8%)	2 (1%)
8	Referral of patients to another clinic	0	6 (15%)	1 (3%)	1 (2.5%)	8 (7%)	8 (6%)
9	The number of patients placed in intensive care whose parents left the clinic with a signature	0	0	0	1	1 (0.8%)	1 (1%)

In addition, Table #3 lists the most common diagnoses and diseases that result in hospitalization for patients. It also notes that patients from all clinics that are pertinent to the research task (requiring emergency care) were included in the study.

ICD- 10	Diagnosis	Intraosseous approach	Intravenous approach	Total
I 46	Cardiac arrest	2		2
R 56.8	Unidentified and other convulsions		14	14
G 41	Status epilepticus	12	10	22
R 57	A shock not covered by another rubric		27	27
R 57.1	Hypovolemic shock	8	25	33
R 57.9	Shock, unspecified		31	31
T 79.4	Traumatic shock	3	6	9
R 40.2	Coma, unspecified	1		1

 Table #4. Nosologies and total patients enrolled in the research based on

 clinics

This was deemed noteworthy since the circumstances that drive the patient to the clinic might have a big impact on the clinical management strategy, in addition to the "speed" at which therapy is started.

Table #4 illustrates the degree of comparable between the previously indicated prerequisites (nosologies/conditions) among the groups we

presented. This indicates that all of the study's participating clinics saw a similar number of patients with the same diagnosis.

It was also thought to be significant to analyze the research findings in light of overall national data, namely the requirement for hospitalization. We are referring to the comparison between the research target group's prehospital and pre-hospital diagnoses.

	2018 Year		2019 Year		
ICD-10	Diagnosis	Number of emergency calls	Number of hospitalizations	Number of emergency calls	Number of hospitalizations
I 46	Cardiac arrest	6	5	3	1
R 56	Convulsion not included in other rubrics	1022	750 (73 %)	898	671 (75%)
R 56.8	Unidentified and other convulsions	0	0	2	2
G 41	Status epilepticus	33	29	39	27
R 57	A shock that is not included in other rubrics	2	2	2	2
R 57.1	Hypovolemic shock	1	1	1	1
R 57.9	Shock, unspecified	1	1	1	1
T 79.4	traumatic shock	11	9	6	6

 Table #5. Nosological distribution of patients by the emergency medical assistance brigade.

 Table # 5 describes the above, from which it can be seen that in 2018

 2019, among the reasons for calls to the apartment and hospitalization by

 emergency medical services, those conditions are likely to require IO at the

pre-hospital stage. According to the same figure, among patients in the age range under study, convulsive states account for a significant portion of calls to the apartment and, consequently, hospitalization (73% in 2018 and 75% in 2019). It is important to remember that, on the one hand, the IO approach was not introduced for patient management during the prehospital phase, and that any convulsive condition always calls for quick action and an intravascular approach, both of which are impossible due to apparent reasons (peripheral spasm during cardiac arrest, frequently inexperienced medical personnel, etc.). On the other hand, the IO approach is typically used for this. Our data (see Table #6), which shows the largest need for intraosseous catheterization, confirms this.

Determining whether staff members required retraining and repeated training was one of the research's objectives. For this reason, we split the doctors into two groups: one group applies this methodology in practice after training, whereas the other group does not.

The training's objective was to equip the physician with the know-how and abilities needed to carry out intraosseous infusions successfully in the appropriate circumstances.

The educational program of this training can be characterized as follows in terms of organization and content:

(i) A brief interactive lecture covering the principles, algorithm, indications (such as when IV access or resuscitation is impossible), contraindications (like non-intact bone), and the ideal placement for the IO catheter to operate well (such the proximal region of the greater tibia)

(ii) Practice: One instructor for every four participants, IO kits for each participant, and skill stations with plastic bones. Following the demonstration, each subject receives the fixation technique in addition to a complete IO infusion.

After a hands-on demonstration of the skill, it is imperative that each participant receives feedback in order to successfully manipulate the IO catheter.

Staff testing was conducted before training (pre-test). Additionally, corresponding post-testing was carried out, and the outcomes were contrasted.

It is evident that the training was effective when comparing the pretest and posttest results. The clinical, theoretical, and practical abilities required for practice were gained by doctors. It was thought that initial training would be necessary but optional for the use of such methods. According to Table #6, which shows a statistically significant difference between tests. It is also important to note that the training was attended by emergency physicians, the majority of whom were female, and one guy, with two to five years of medical experience.

	Average	Quantity	Standard deviation	Standard error of the mean	Sig.
pre test	7.62	26	4.500	.882	.001
post test	13.88	26	5.309	1.041	

Table 6. Statistics of paired samples pre and first post test

When it became hard to provide IV catheterization and all indications were for intraosseous catheterization, five of the skilled physicians actively treated severe patients using the proper approach over the course of the following year (prior to retesting).

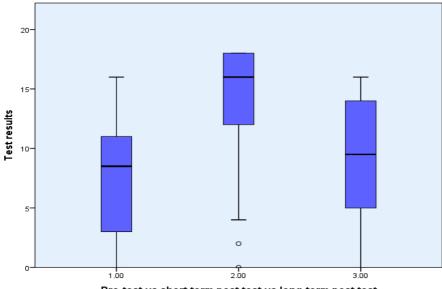
When the results of the first testing and the repeated testing (long-term) were compared, it was evident that the individuals who could apply the knowledge and skills they had learned during the course (see Table 7) were able to retain them as well as the ability to be "ready" for such practice. To enable comparisons between the scores of the participants who underwent the intraosseous catheterization procedure after the course delivery, for the long-term control before the post-test, and among those who did not perform such a procedure during this period (did not perform it under other equal conditions) and/or who were not given the opportunity to do so, a paired sample t-test and an independent sample t-test were specifically used for the comparative analysis of the pre-test and post-test scores (see table #7).

 Table # 7 - Statistics using paired samples for pre- and long-term post-test

 comparisons

	Average	Quantity	Standard deviation	Standard error of the mean	Sig.
Pre - Test	7.62	26	4.500	.882	.024
Long-term post-test	9.65	26	5.051	.991	

As it was expected, table #7 demonstrates that test scores tend to decline with time. Furthermore, the ideal time frame for retraining was identified for individuals who infrequently employ the intraosseous technique in practice (for any reason); based on our data, this window of time is one year. The research revealed, in particular, that retraining is required for workers in the category who do not utilize this type of practice to be prepared to apply it, and that the requirement for recurring retraining should be set at a minimum of one year.



Pre-test vs short term post test vs long-term post test

Figure #1 Results of pre-test, short and long-term training of the personnel involved in the study.

Table #7 and Figure #1 describe differences between groups; In particular, our results show a statistically significant difference between the pre-test (mean: 7.62, SD: 4.5) and post-test (mean: 9.65, SD: 5.05) groups (p

< 0.001), as well as short-term between the post-test and long-term control post-test groups (mean: 13.88, SD: 5.3) (p < 0.05). As expected, test scores decline over time, and this decline is statistically significant.

Although the results of this group and the group itself differ from other clinic data, it is evident that the composition of the #1 clinic group is not homogeneous with respect to the subject under study (reliable P<0.001); it is noteworthy separately that there was a difference between the doctors involved in the study in the clinic (#1) in terms of using the knowledge/skills obtained through training. It is also noteworthy separately that the young members of the group are highly motivated to implement such practices. A portion of the aforementioned subgroup lags behind the other group members (who utilized intraosseous catheterization in practice); this further supports the reasons for the variation in results (between the groups) (within the group not "using" it in practice) and the necessity of training separated by a year. This group's average age is between 30 and 40 years old.

Review

Intraosseous catheters are used when peripheral vein catheterization is difficult or impossible, and in some clinical situations, they are a safe and alternative way to introduce medications and infusion solutions, as demonstrated by contemporary scientific literature and advanced country practice (4,5); Our research's data further supports this. Table #3 confirms that "not using" this practice, in particular, hinders (makes less effective) the quality of medical care and the patient's condition outcome. Our study, however, demonstrated that, ceteris paribus, clinical outcomes (death, 24-hour ICU delay) in managing pediatric emergencies are better in clinics where this practice is used (see table #3). The "safety" of the suggested alternate procedure is also crucial because there haven't been any infection-related issues.

Additionally, we can assess how cost-effective it would be for the clinic and the state to apply this methodology in the field of pediatric emergency care, not just for the pediatric contingent, based on the data that was obtained—even when considering the cost of an ICU bed (10–15).

Implementation of the IO approach, both at the pre-hospital and hospital level, will significantly improve the quality of life saving, which is reflected in the later stage of post-resuscitation conditions. Although our study did not manage to evaluate the possible results of using the studied manipulation at the prehospital stage, the indicators shown in Table #5 show how high (in the total number of calls) the percentages of the need for hospitalization or intensive care unit placement, which could have been "low" due to the

reasons for these calls (convulsive conditions in 73%-75%); Accordingly, according to the data we received, there is a well-founded opinion that the benefits will be more "obvious" when introducing the practice of intraosseous catheterization at the pre-hospital stage (4-20).

Therefore, all of the aforementioned findings from our study, along with data from other researchers based on cost-effectiveness and/or clinical outcome, support the necessity and advantages of an alternate strategy to intravenous catheterization (1-4). Consequently, pediatric patients experiencing different forms of shock, status epilepticus, and cardiac arrest will benefit from the pre- and intra-hospital application of this approach. which, if it is fully implemented, will undoubtedly contribute to a long-term decrease in the death rate among these patients (16).

Knowing how to administer an intraosseous injection may help emergency medical staff avoid deteriorating the patient's condition further because they won't have access to an intravenous line. It is also significant to note that one of the primary benefits of intraosseous catheterization is that it is a practical skill that can be learned quickly, requires little to no equipment, and is frequently utilized by medical professionals with the necessary training. When intravenous catheterization is not feasible for a variety of reasons, this study will let emergency physicians use this technology and use it on critically ill patients (30–35).

An intriguing correlation was discovered between the doctor's age and years of medical experience, as well as the use of the methodology. The results of the study showed that the intraosseous catheterization approach is utilized more frequently and with greater ease by doctors who are younger and have less clinical experience (33).

One of the main objectives of our study is to develop a scientifically based approach to the implementation of intraosseous catheterization; consequently, one of our tasks was to train or retrain medical personnel. Additionally, we needed to conduct targeted research to ascertain how frequently the medical staff needed to provide intraosseous catheterization.

We assumed that if the use of intraosseous injection in the practice of the doctor will be active, it will be enough for this category of doctors to conduct repeated training in practice every two years, as is done in developed countries, where intraosseous catheterization is widely used in practice. In addition, the results of our research showed that in the countries of the type of clinical practice (e.g. Georgia) where this technique/manipulation is not routinely performed, i.e. in the initial period of implementation, it should be provided to medical personnel who do not use it at least once a year (50- 55).

Conclusions

1. Intraosseous Catheterization Improves Quality of Emergency Findings and Outcomes in Pediatric Patients.

2. According to the results of our study, the use of an alternative approach to intravenous catheterization in pediatric patients with such indications is "safe" and practically does not cause complications.

3. Research has shown that the use of an intraosseous catheter in emergency pediatric patients increases cost-effectiveness (based on the need for delay in resuscitation).

4. The research showed that convulsive conditions are the most frequent reasons for the need for emergency care in the pediatric population of Georgia, which indicates the need to introduce the use of intraosseous catheterization techniques at the prehospital stage.

5. According to the results of our research, the medical personnel easily master the mastery course of the intraosseous catheterization technique, although the "readiness" of the said personnel is not a sufficient prerequisite for its implementation in the clinic.

6. The study determined that medical personnel who do not practice intraosseous catheterization require retraining, and the timing (retraining) differs for countries where implementation is in the initial stages.

Practical recommendations

1. Practice shows that an intraosseous catheter is used when peripheral vein catheterization is difficult or impossible, and it is a safe alternative way to introduce drugs and infusion solutions in certain clinical situations.

2. This method is expected to significantly reduce the mortality rate during critical and emergency situations in the pediatric population

3. Intraosseous catheterization will also be useful for improving the quality of medical services and ensuring patient safety in an inpatient medical facility.

4. Also, the results of the research are important for both Tbilisi and the region of Georgia.

5. It is important to introduce educational programs in terms of developing practical skills of intraosseous injection, both for those with pre-diploma and post-diploma medical education.

A list of papers and publications on the dissertation subject given at international scientific conferences.

List of published publications:

1. Nino Kikodze (PhD Student) a Ketevan Nemsadze (Professor), Pediatric Emergency Cases Managed with Intraosseous Access: Indications, Complication and Outcomes International Journal of Sciences: Basic and Applied Research (IJSBAR) 2019, Volume 47, No 2, pp 22-30

 Nino Kikodze, Ketevan. Nemsadze, Gvantsa Togonidze, Ilia Nadareishvili, Intraosseous Access Use in Pediatric Emergency Care in Georgia, Georgian Medical News, No 2 (299): 33-38;

3. Kikodze N., Nemsadze K., Anuoluwap O., Enoch O., Intskirveli M., **The short and long-term impacts of Intraosseous catheterization training on medical staff's readiness to stabilize critical patients at the pediatric Emergency Department**. Georgian Medical News, No 2 (309): 180-183;

5. Nino Kikodze, MD and Ketevan Nemsadze, MD, PhD., Integration of Intraosseous Approach Method in Georgia, Pediatric Emergency Care
Volume 40, Number 2, February 2024:147-150 pp.