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A Comparison of Outcomes for Lipid Emulsions in Total Parenteral Nutrition Among Home Infusion Patients

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Abstract

This quality improvement project aimed to compare the outcomes of lipid emulsions used in total parenteral nutrition among home infusion patients. The quality improvement project included 45 patients who received four weeks or more of either Intralipid or SMOFlipid. Paired t-tests were used to compare SMOFlipid and Intralipid regarding three liver function test (LFTs) values; (Alkaline Phosphate (ALP), Aspartate transaminase (AST,) and Alanine transaminase (ALT). Results demonstrated that SMOFlipid was superior to Intralipid, resulting in lower LFTs for ALP, AST, and ALT. This study provides evidence to support the use of SMOFlipid over Intralipid in total parenteral nutrition for home infusion patients.

Introduction

Nutritional support for individuals with conditions requiring long-term intravenous nutrition can be challenging, and providing adequate nutrition can be difficult when dealing with limited nutritional options available through enteral nutrition via enteral tube feedings. Total parenteral nutrition (TPN) has become an important part of the nutritional support of these patients in recent years. Although the use of TPN has been increasing, concerns have emerged regarding how to provide a balanced formulation and reduce the risk of complications or adverse consequences. One area of particular concern is providing an adequate lipids source for these patients that does not result in persistent rises in LFTs.

This report will examine the strategies for providing lipids in TPN in home infusion patients and compare the outcomes for lipid emulsions in different formulations. Home infusion is defined as providing intravenous therapies, including nutrition at home instead of inpatient settings, including home healthcare delivery and institutional delivery, such as nursing homes. Specifically, this report will compare lipid emulsions' effectiveness and safety outcomes via identical delivery systems among home infusion patients receiving TPN.

Problem Description

Home infusion services for TPN are utilized by many people who suffer from severe intestinal malabsorption, such as short bowel syndrome (SBS), intestinal failure-associated liver disease (IFALD) secondary to short bowel syndrome, cystic fibrosis, Crohn’s Disease, enteropathies, as well as other conditions which involve malabsorption, to ensure proper sustenance of nutrition (Aksan et al., 2021). Such individuals necessitate frequent commensurate

monitoring of their nutritional status, where a major component of their daily intravenous TPN formulation comprises lipid emulsions; these emulsions need to be delivered by aseptic means for optimum safe nutrient intake. To better understand the efficacy of home infusion services for malabsorptive syndromes, pertinent sub-topics may include an evaluation of the specific requirements for nutrient absorption in SBS patients, the importance of parenteral nutrition and lipid emulsions for sustaining individuals with malabsorption and their qualitative analysis, as well as exploring the avenues to maximize efficient nutrient utilization while ensuring adherence to safety parameters. It is key to analyze how these components work in synergy to effectively reach optimal levels of nourishment and well-being in patients undergoing home infusion services (Lowe, 2020). To this end, one may evaluate various studies in medical literature to elucidate further how this treatment protocol operates at different capacities for different conditions and the efficacy of parenteral nutrition and lipid emulsions for nutrient absorption by SBS patients. Additionally, qualitative approaches for investigative evaluation of the efficacy of parenteral nutrition and lipid emulsions for those with malabsorption also be discussed. Furthermore, approaches for efficient nutrient use by patients undergoing home infusion services, such as dietary management and lifestyle change, can also be explored.

However, the delivery of lipids via TPN has presented certain challenges which may induce complications if not monitored and managed effectively. For instance, if a patient receives too much fat/lipid or oil-based lipid emulsion, this can lead to elevated triglyceride levels or even fat overload syndromes, such as hyperviscosity or HTGP and parenteral nutrition-associated liver disease (PNALD). This risk is further compounded by the potential for hypersensitivity reactions due to many lipids' bioactive components, such as omega-3 polyunsaturated fatty acids (PUFAs), phytosterols, and the added Vitamin E. Such an overload of

lipids may sound alarming; however, any potential toxicity from a TPN prescription can be well contained when appropriately managed. The introduction of too much fat into the diet can be detected quickly and monitored through biochemical parameters such as blood triglycerides. Hyperviscosity and its associated HTGP are most seen with prolonged high doses of TPN containing large amounts of fat emulsion, as is parenteral nutrition-associated liver disease (PNALD). It is imperative to monitor the lipid emulsion in the TPN mixture, with particular attention to the amounts taken in over any given period. One way to minimize any potential adverse effects is to slowly increase the doses of TPN over time and monitor the Total Essential Fatty Acid intake levels relative to caloric intake. This is generally achieved prior to discharge to home in a process known as TPN cycling.

Hypersensitivity reactions due to elements within TPN mixtures are also a concern that should be closely monitored by healthcare provider personnel (Boullata et al., 2021). These occur more rarely than the more common occurrences of fat overload syndromes (PNALD) and have been detected in children and adults who have been administered TPN-containing PUFAs. Unsafe increases in LFTs and/-or triglycerides should prompt protocols for adjusting TPN, or even replacing it with another form of nutrition delivery upon clinical observation or any suspicion of an allergic reaction or hypersensitivity response resulting from its bioactive components.

Lastly, because TPN is generally utilized for those with a compromised gastrointestinal system and those in long-term treatment, there is also an increased risk for infection from any foreign object administered intravenously through their central venous access. ASEPSIS protocol should be strictly adhered to when administering TPN continuously reduce any potential entry points for microorganisms into the bloodstream as much as possible, as well as performing

comprehensive tests prior to each dose to determine any contamination or toxicity levels present prior to infusion (Sastry & Deepashree, 2019). The danger that may arise following the administration of lipids via TPN can be effectively managed by healthcare personnel if they are mindful of all the necessary parameters to keep in check throughout the process of administering these compounds, thus ensuring an optimal nutritional delivery system without exposing patients to unnecessary danger or risk (Caro-Bautista et al., 2021).

Available Knowledge

The administration of lipid emulsions as part of Total Parenteral Nutrition (TPN) is complex, requiring careful consideration of the multiple components involved in formulating an effective emulsion, and overall final TPN product. Previous clinical studies have extensively explored the effects of intravenous lipids and their associated benefit in specific indications. These research studies have indicated that certain formulations of lipids, such as those with omega-3 polyunsaturated fatty acids (PUFAs), phytosterols, Vitamin E, or other antioxidants, may be particularly beneficial. Omega-3 PUFAs present in many lipid emulsions offer antioxidant benefits for the body, thus conferring a protective effect on cells from free radical damage and therefore promoting the anti-inflammatory response. Omega-3 fatty acids also have cardiovascular benefits that may reduce the incidence of cardiovascular abnormalities and mortality (Djuricic & Calder, 2021). Phytosterols are plant-derived sterols commonly found in vegetable oils. They have been proposed as useful components of lipid emulsions due to their potential role in regulating inflammation and enhancing immune functions. Vitamin E is an important antioxidant, which scavenges free radicals present in lipid emulsions and provides protective effects against oxidative damage.

Selecting an adequately balanced emulsion is crucial for optimal TPN effects. Studies have shown that excessive and prolonged exposure to intravenous lipids or PNALD can disrupt normal cell physiology, causing inflammation and microvascular dysfunction in multiple organs and leading to other complications such as impaired hepatic glucose metabolism, disruption of tissue lipids, and increased morbidity. Additionally, lipid emulsions are thought to influence how some drugs are delivered and assimilated within the body and thus should be used cautiously in patients taking certain pharmaceuticals. It is also important to consider the method of administration, which can include bolus infusion, manual addition during TPN preparation, infusion in a continuous lifestyle, or automated addition through a delivery system, each potentially impacting accuracy and safety of TPN delivery. Optimization of lipid compositions and the dose and frequency of lipid infusion have been suggested to enhance patient outcomes and reduce potential short- and long-term complications arising from lipid emulsion infusions.

Evidence from a systematic review conducted by Pang et al. (2019) has confirmed that an adequate intake of long-chain omega-3 polyunsaturated fatty acids (PUFAs) present a range of beneficial effects on intestinal immune functioning and a reduction in the risk of decaying health due to lower gastrointestinal tract conditions such as Crohn's disease and ulcerative colitis. Notably, these PUFAs can provide therapeutic benefits with minimal adverse risks, providing the recommended dosages are adhered to. This is further reinforced by numerous case reports demonstrating the potential to utilize PUFAs at higher dosages in certain home infusion applications without the detriment of toxicity or irritation. This further reinforces the assertion that omega-3 PUFAs have real clinical potential as an effective intervention in a range of gastrointestinal conditions whilst being of lower risk to those with healthy pre-existing conditions.

Remarkably, omega-3 PUFAs have been found to possess a broad range of potential health benefits, such as maintaining ocular health, cognitive capacity, and improved mental well-being and promoting a balanced inflammatory response (John & Singla, 2021). Omega 3 PUFAs are, therefore, a good nutritional resource that should be utilized when appropriate and is suggested to be highlighted to individuals of all age groups to enhance general well-being and promote gastrointestinal health.

Due to the broad evidence base practices supporting the use and utilization of long-chain omega 3 PUFAs for their therapeutic potential, it is generally accepted that omega 3 PUFAs should be considered when addressing a range of gastrointestinal conditions. Indeed, current dietary and health guidelines often recommend an adequate intake of omega-3 PUFAs to improve overall health and well-being, therefore highlighting their significance. With widespread recognition of the risk of nutritional deficiencies, the augmented advantages of omega-3 PUFAs present an attractive and viable alternative to reduce this risk (Martucci et al., 2020).

Currently, two specialized fat emulsions available under prescription for adult use with Total Parenteral Nutrition (TPN) – Intralipid® (Baxter) and SMOFlipid® (Fresenius Kabi) – are proving to be particularly beneficial in providing balanced nutrition with a low concentration of several compound groups, including omega-3 fatty acids, phytosterols, minerals, and vitamins. Known to be associated with an improvement in metabolic control and a decreased risk of antibiotic resistance in medical populations, these formulations represent an advancement in the field of parenteral nutrition. By providing high-quality fat emulsions in addition to other sources of carbohydrates (dextrose) and proteins (amino acids), patients receiving TPN can gain access to a broader range of nutrients and prevent nutritional deficiencies. Furthermore, the presence of essential micronutrients, including vitamins, minerals, and trace elements, contributes

significantly to the quality of overall nutrition; this is further demonstrated by the fact that phytosterol – a compound found in plants that demonstrates anti-inflammatory properties – has been included in low concentration to mitigate the effect of chylomicron formation from long-chain fatty acids. Finally, omega-3 fatty acids – another group of essential fatty acids also found in smaller concentrations in both formulations – offer additional benefits as part of a healthy eating pattern for adults, especially when it comes to cardiovascular health. As a result, these parenteral fat emulsions offer an advanced nutritional solution for adults receiving TPN, addressing multiple nutrition needs while minimizing potential risks.

In addition, regarding home infusion patients receiving nutritional support delivered by TPN, recent work has proposed an operational definition that seeks to delineate more precisely the parameters under which these patients receive their nutrition support. The stated definition, structured by Committee on Home Care Services (CHCS), outlines the scope and extent of management to provide parenteral nutrition support in both adult home healthcare settings and those employed in institutional or nursing home settings. This definition denotes a heightened level of observation and evaluation to take place prior to offering nutritional assistance via TPN, to ensure adequate preparation for the process, for example, by identifying potential issues related to metabolic balance and fluid/electrolyte levels as well as by assessing any potential side effects that could be experienced as a result of administering such nutrition (Rodenbaugh et al.,2020). Furthermore, the recommended definition accounts for patient-specific clinical factors, such as comorbid medical conditions, that should be considered when offering such support. Indeed, the structure exhibits an acute sensitivity to the multi-dimensional aspects integral to parenteral nutrition support within home settings for at-risk populations.

Finally, the definition categorizes TPN administration as a medical intervention requiring regular monitoring and follow-up certification from credible healthcare personnel; this view firmly signals that parenteral nutrition support in home settings should deviate from being considered a simple administrative decision-making process to one that reflects advisory consideration of professionally trained and registered healthcare personnel with the appropriate credentials to evaluate the suitability and safety of commencing nutritional support. Furthermore, by proposing a comprehensive operational framework to support the decision-making process regarding TPN administration, the proposed CHCS definition offers an enduring structure with which home care services can utilize in offering nutritional assistance to manage patient health and wellbeing effectively (Murney et al., 2020).

Rationale

The rationale for this quality improvement project arising from two sources, in aiming for a more comprehensive understanding of how different lipid emulsions are absorbed from TPN among home infusion patients, starts from the belief that such insight could provide direction for best practices when providing intravenous TPN for those with intestinal failure disorders, as well as potentially allowing beneficial outcomes such as reduced reaction severity or improved systemic outcomes, specifically lower LFTs. This potential to alter existing order sets prescribed to formulate TPN across Penn Home Infusion Therapy (PHIT) through informed decisions based on their level of effectiveness is what makes gaining a greater awareness of the physiological impacts of lipid emulsions so desirable. Moreover, by understanding the varying degrees of absorption and impact on LFTs of certain lipids and how they can be optimally incorporated into TPN, it may be possible to provide improved treatment plans which enhance the patient experience and improve their prognosis, as TPN plays a prime role in preventing

malnourishment (Rădulescu & Lundgren, 2019). Thus, in recognizing the influences of lipids on absorption, it is hopeful that solutions can be provided which accommodate both patients' needs and provide what is most beneficial in terms of the efficacy of the TPN course.

Furthermore, effective absorption of fats in TPN may indicate good nutrient delivery, as fats/lipids are essential macronutrients that participate in a complex array of functions throughout the body. Knowledge of lipid emulsion stability can also bring insight into how well the nutrients are being delivered to the systemic circulation, allowing alteration to treatment plans where required and ultimately improving patient care (Manocha et al., 2022). The notion of being able to enhance or modify treatment plans is not one to be taken lightly, as it could lead to improved therapeutic outcomes through conventional therapies and rehabilitation pathways in a much more targeted and precise manner than may have been anticipated previously. Although this study has great potential, it still needs to be determined how much this insight can help change patient care in the long term. However, it could be of real benefit to those with intestinal failure disorders who depend on TPN for their nourishment and care.

In order to achieve its proposed aims, this project utilizes a funneling method of knowledge gathering grounded in the Knowledge to Action (KTA) Model developed by Graham et al., which takes into account the full spectrum from research assessments through evidence appraisal, involving a rigorous examination of the existing evidence related to the subject matter, and reaching to knowledge exchange and ultimately practice change. The KTA Model is particularly effective when used in medical decision-making, given its potential to incorporate both theories and practical applications of research data, which is why it has been adopted as the common methodology for this quality improvement project. This method first involves identifying relevant case studies according to criteria set by CHCS for determining the likelihood

of an occurrence of hypersensitivity, as well as undesired outcomes such as PNALD/unnecessarily high LFTs, and subsequently performing an evidence appraisal. This allows for an understanding of how likely any formulation may cause undue risk to inform better practice decisions. Finally, the results of this appraisal will be consolidated, along with other pertinent information, including cost considerations, to deliver a recommended formulation that can be used with confidence and maximum efficacy in clinical contexts.

It is important to note that this project also considers the impact that the cost of any given formulation may have on the results, something which was previously neglected in prior studies on this topic, and which can have meaningful implications on both the safety of patients and the efficacy of treatments. This further highlights the importance of combining theory with practice to inform the delivered recommendations. For example, in cases where higher-risk formulations may be necessary, consideration should be taken when deciding on the affordability of any option. In such cases, the evidence should strongly suggest that there is no undue risk associated with a particular formulation and that it is economically feasible to ensure the best possible outcome for patients (Temesgen et al., 2021).

Specific Aims

The specific aims of this project include the following:

• To conduct a retrospective chart review evaluating levels of liver enzyme transaminases~~,~~ and alkaline phosphatase—liver function tests (LFTs) among home infusion patients admitted to Penn Home Infusion Therapy (PHIT) receiving different lipid emulsion formulations over consecutive time periods is an effort to provide insight into the effects of these different formulations on LFT levels. Since demonstrating the direct role of the medications in causing various physiological changes impacting liver enzymes has been a difficult task, this

project seeks to analyze if there are differences in LFT levels between the various home infusion patient cohorts over successive monitoring periods. Thus, it will help to uncover differences in the metabolism and effects of these medications, providing information that can help to establish pharmacokinetic relationships between drugs and metabolic changes within the body. The ultimate aim of this project is to enable clinicians to better predict and manage potential side effects related to these intravenous TPN therapies.

• To evaluate any hypersensitivity reactions that may be present and their severity level in home infusion patients who are receiving various formulations, an assessment of the adverse reactions must be conducted. This assessment should include reviewing the patient's medical chart for history, physical examination, and laboratory testing to determine the patient's initial baseline values and monitor for laboratory deviations. Additionally, any adverse reactions should be noted and documented, along with all pertinent clinical data, including notes on signs and symptoms, administration site, treatment process, and outcomes. Careful consideration must be taken when analyzing the data to differentiate between adverse drug reactions, non-drug-related adverse events, and hypersensitivity reactions to reach a definitive conclusion.

• To robustly evaluate established models of practice used in home infusion services to identify optimal lipid emulsion sources when designing and establishing Total Parenteral Nutrition (TPN) formulations, this project will make a systematic analysis of the current evidence-based data, coupled with a careful evaluation of both the quality and quantity of medical professionals' current practices. By carefully analyzing both the medical and nursing literature on TPN formulation and systematic reviews of therapies often employed in home infusion services, this project will attempt to clarify the factors likely to influence optimal lipid source selection. Furthermore, informal interviews conducted among medical practitioners

currently employed in home infusion services and or clinical nutrition practice will lead to deeper insights into how decisions regarding lipid emulsions are informed and enacted in contemporary practice. The results of this project will not only inform effective sourcing of optimal lipid emulsion products for TPN formulations and allow for the design and implementation of more structured, evidenced-based practices for determining fatty acid sources in home infusion services.

• To develop comprehensive clinical practice recommendations informing the selection of optimal lipid emulsions for use in Total Parenteral Nutrition (TPN) formulations for home infusion patients at Penn Home Infusion Therapy suffering from intestinal failure disorders, an interdisciplinary approach should be adopted. Such an approach requires a comprehensive assessment of the patient's nutritional needs through careful consideration of a range of clinical parameters such as pre-existing conditions, nutrition-focused physical assessment (NFPA) results, and estimated energy requirements. This approach also requires an in-depth review of current evidence from clinical studies and trials, where available, to evaluate which lipid sources demonstrated the greatest efficacy for achieving positive patient outcomes. In light of potential differences between individuals, due care and consideration should be given to each patient's specific circumstances and needs when selecting an appropriate lipid product. Additionally, with limited evidence or consensus on optimal practice within the literature, recommendations should be based on reasonable conjecture and extrapolation from the best available evidence only. Once a safe and effective method of delivering nutrients to the home infusion patient is identified, nutrition professionals must minimize any errors or omissions in implementing such a regimen to protect patient safety and ensure best practices are adhered to. As such, close consultation with

dietitians should be established with regular review of intervention strategies to optimize the performance of treatments moving forward.

Methods

Context

When introducing the intervention of lipid emulsions for total parenteral nutrition to home infusion patients, several contextual elements are important to consider. First, the health of the patient should be assessed to determine if they are able to tolerate the lipid emulsions and their administration. Additionally, the type of emulsion being used should be determined, as well as the total amount of lipid needed to be administered to the patient. Furthermore, it is important to consider any potential adverse reactions that the patient may have to the lipid emulsion, such as anaphylaxis or other allergic reactions. Patients with a history of allergic reactions to fish/seafood would be excluded from receiving SMOFlipid as it contains fish oil. Several studies have found that patients receiving TPN may experience poor health outcomes due to increased sensitivity to specific allergens in the formula. (Araujo et al. (2018); Christian et al. (2018); Hernández et al. (2016); Leguina-Ruzzi and Ortiz (2018); Pang et al. (2019). By raising awareness of the critical role of nutrition in promoting patient well-being, healthcare providers may be able to mitigate the adverse effects of TPN on patients' health.

Additionally, the cost of the emulsion product should be considered to determine if it is a cost-effective option for the patient in cases of out-of-pocket payments, as well as the financial impact on the entity. The most recent cost analysis can be classified as:

The average ml per TPN is 1600 ml. AWP (Average Wholesale Price). Obtaining it from Lexicomp, the costs were as follows:

1. Intralipid 20%: $0.23 per ml
2. SMOF 20%: $0.12 per ml

McKesson (our wholesaler), the costs were as follows:

1. Intralipid 20% 1000 ml bag – AWP $528.74 - $ 0.53 per ml
2. SMOF 20% 1000 ml bag – AWP $453.60 - $0.45 per ml

This current cost evaluation is largely the inverse of standard costs. Historically, Intralipid is less costly than SMOFlipid. This change is welcome as it provides additional benefits to both patients and PHIT.

There was a cost of less than $300 dollars for statistical analysis services, and the materials, such as printing and making copies and disseminating materials for all stakeholders. Copies of the quality improvement final report and a PowerPoint presentation of the highlights of the project will be provided to all participants. The project leader sought permission from PHIT management to conduct the quality improvement project at the organization, and all associated project costs were covered by the relevant stakeholders. The healthcare organization attorney assigned to manage scholarly projects, dissertations, and capstone projects for educational purposes reviewed an email sent by the project leader to confirm there was no requirement for an institutional review board (IRB).

The costs of the project were budgeted to be minimal. There were two categories of stakeholders. Internal stakeholders included the home infusion patients receiving TPN services through PHIT. These individuals did not have access to any information that could potentially harm the data collection or analysis. External stakeholders were those that were affected by the

outcomes of the internal organization change of policies regarding the use of lipid emulsion products for maximum patient safety, such as PHIT clinicians/employees who care for home infusion TPN patients.

Intervention

To start the intervention, the RNs, CRNPs, a PhD-prepared dietician, MD, and who regularly work with the TPN patient population were educated on the project goals, implementation strategy, and the specific usage of LFT monitoring and recording once the intervention is put into place. As part of the standard protocol for home TPN patients, LFTs including AST, ALT, and ALP were drawn weekly as per protocol for PHIT TPN patients, as well as for patients who have received a product change, and the findings can be trended reliably to minimize the risks associated with the introduction of a new lipid emulsion. The data was collected during and after implementing the intervention, and was compared to prior results, and a comprehensive examination of the underlying cause of the response was conducted.

The intervention studied was the use of lipid emulsions in total parenteral nutrition (TPN) among home infusion patients. The two lipid emulsions compared were Intralipid and SMOFlipid. Patients who were currently receiving TPN through the project timeline and met the inclusion criteria were included in the project unless any serious risks were observed earlier. Patients in this study were required to receive a minimum of 4 weeks of either Intralipid or SMOFlipid in order to be included in the results. The study also included patients who had to switch from one lipid to another due to a lipid shortage. The data collected and analyzed focused solely on TPN patients receiving care from PHIT. The DNP student who led the project was the person responsible for complying with all requirements associated with conducting chart reviews

and data collection with human subjects involved to ensure ethical considerations when involving human participants in research.

The team involved in this project comprised a registered pharmacist/PharmD, a certified registered nurse practitioner further certified in clinical nutrition support, the director of Pharmacy, and the University of New Hampshire Nursing faculty. All employees at PHIT who provide treatment to patients receiving TPN infusions at home were not required to participate in the project team. However, home infusion nurses were a crucial part of the success of the quality improvement project and are included as essential members. The team was responsible for collecting data on the outcomes of patients receiving the two different lipid emulsion products in total parenteral nutrition (TPN) while considering their physiological condition/disease state and tolerance levels for the various interventions. A select group of individuals from PHIT and/or Penn Medicine were also chosen to informally participate in the project and received topic insight, up to comprehensive information about its objectives. Additionally, the team was responsible for communicating the data of the study to two practice partners.

Study of Interventions

The approach chosen for assessing the impact of the intervention was a comparative analysis of the outcomes of patients receiving either Intralipid or SMOFlipid as part of their total parenteral nutrition admixture. The primary outcome measure used was the change in the three liver function tests (LFTs) from baseline to the end of the 4-week intervention period for each lipid product. In order to assess the effectiveness of the interventions on the TPN patient population under examination an Excel spreadsheet was initiated to record and track LFTs. Weekly evaluations of the LFT comparisons were collected and examined to determine the degree of variability present in the results. Additionally, a retrospective chart review was

performed by the practice partners to compare patients who were switched from one lipid product to the other while receiving TPN at home before and after the intervention during a national lipid shortage. This tool was valuable in determining whether the observed improvements are a result of the implemented interventions.

Measures

The primary measure chosen for studying the processes and outcomes of the intervention was lipid emulsions and subsequent resulting LFT values. Specifically, the two lipid emulsions used were Intralipid and SMOFlipid. The rationale for choosing this measure was to compare the outcomes between the two lipid emulsions in terms of their effect on liver function tests (LFTs), including alkaline phosphatase (ALP), aspartate aminotransferase (AST) and alanine aminotransferase (ALT). The operational definitions of the two lipid emulsions were based on the product labels and their general definitions/categorization. The validity and reliability of the measure were assessed by comparing the results of the LFTs from the patients who received 4 weeks or more of either lipid emulsion.

The approach to the ongoing assessment of the contextual elements that contributed to the success, failure, efficiency, and cost of the intervention was to assess the patient's adherence to the prescribed lipid emulsion, the length of time the patient received the lipid emulsion, and the patient's response to the intervention as measured by the LFTs. This was done to determine whether or not the intervention was successful and to compare the outcomes between the two stated lipid emulsions.

The initiative to improve the quality of care was continuously monitored and assessed based on its impact on the standard of clinical care provided. As part of this evaluation, routine,

previously and separately ordered blood samples were collected for LFT analysis to document any potential adverse effects caused by the specific lipid emulsion used for TPN, given the high-risk dietary requirements and the possibility of hypersensitivity to various components of lipid emulsions and TPN in general for the identified patient population. In adherence to the existing PHIT protocol, the patient receiving TPN were to undergo weekly evaluations from visiting home infusion nurses to ensure their safety and well-being, as well as receiving weekly calls from the nurse practitioner from PHIT/clinical nutrition.

The methods employed for assessing the completeness and accuracy of the data were to review the patient's medical records, compare the results of the LFTs over time, and compare the results of the LFTs between the two lipid emulsions. Additionally, the patients who had to switch from one lipid emulsion to another due to a lipid shortage were also included in the data. This allowed for a more comprehensive assessment of the results. The quality of the gathered information was evaluated based on its potential to enhance treatment outcomes, as the primary objective of this project is to elevate the standard of care provided to patients. To achieve this goal, the DNP student and nurse practitioners were accessible to the patient population for any required interventions. Additionally, all PHIT patients are provided a phone number which grants them twenty-four access to a registered nurse and a clinical pharmacist, in accordance with the existing entity protocol.

Analysis

To analyze the collected data, a mixed approach was employed. The DNP student and practice partner utilized specific software of Excel for data collection and management, and quantitative analysis, comparing pre- and post-analysis of LFT results was performed by a qualified statistician. In addition, a qualitative data collection strategy was implemented if

needed for data gathered through the indirect observation of patients' reactions using a shared file. Afterward, relevant data was gathered from the patient medical record numbers/names and de-identified and assigned a number 1 through 45 for the eligible TPN patients through manual data extraction via chart review. The project leader and practice partner stored this information in an encrypted computer file that only they could access. This file was kept in a secure location, accessible only to the project leader and practice partner. After data collection and analysis were complete, the file was deleted to protect patient confidentiality.

Before conducting the statistical analysis, the data were checked for missing values, outliers, and normality. In the case of any missing values, they were identified and rectified. Moreover, outliers may indicate an error in data collection or measurement and may have a significant impact on the results of the analysis. The samples are independent, which means that the samples are not related to each other in any way (e.g., the samples are from different patients). There are no observable outliers present.

Ethical Considerations

Informed Consent

Informed consent is an ethical principle that respects the autonomy and right to decide on research participants. Prior to data gathering it was discussed and considered that each participant was given a consent form, which was tailored to their language and understanding, however, this was deemed unnecessary given no medical interventions were applied to establish this project’s inception or conclusion.

Confidentiality

The ethical considerations of confidentiality and privacy were strictly adhered to in this quality improvement project. All the data that was collected was de-identified to protect the anonymity and confidentiality of participants. Moreover, the data was securely stored, and only authorized members of the research team were granted access.

Risks and Benefits

Any quality improvement, intervention, or research be guided by the principle of balancing risks and benefits. Yip et al. (2016) show that in a study, no individual should be put at risk. In this project, no one was put at risk. This is because the project aims to improve the quality of patient care by improving the nutrition of patients receiving TPN at home and their overall health, namely their LFTs. The project was done on a small scale to ensure that the quality improvement project's pilot program proves effective. There were however some minor risks associated with the intervention analyzed, however, they were not implemented for the interest of this project. This was however mitigated by weekly LFTs that were conducted as per PHIT protocol to monitor any hypersensitive activity and ensure the safety of patients and staff. Therefore, this QI project did not result in any harm to the patients or other staff members.

Results

The aim of this statistical analysis was to compare the outcomes of lipid emulsions in total parenteral nutrition among home infusion patients. Specifically, the comparison was between two types of lipid emulsions - Intralipid and SMOFlipid - in terms of their effect on three liver function tests (LFTs): alkaline phosphatase (ALP), alanine aminotransferase (ALT), and aspartate aminotransferase (AST).

The statistical analysis was carried out using Excel. For the analysis, the question was if SMOFlipid was indeed superior to Intralipid by a measure of resulting in lower LFTs.

The claim was that SMOFlipid is superior to Intralipid in terms of resulting in lower LFTs (Alkaline phosphate, ALT, and AST).

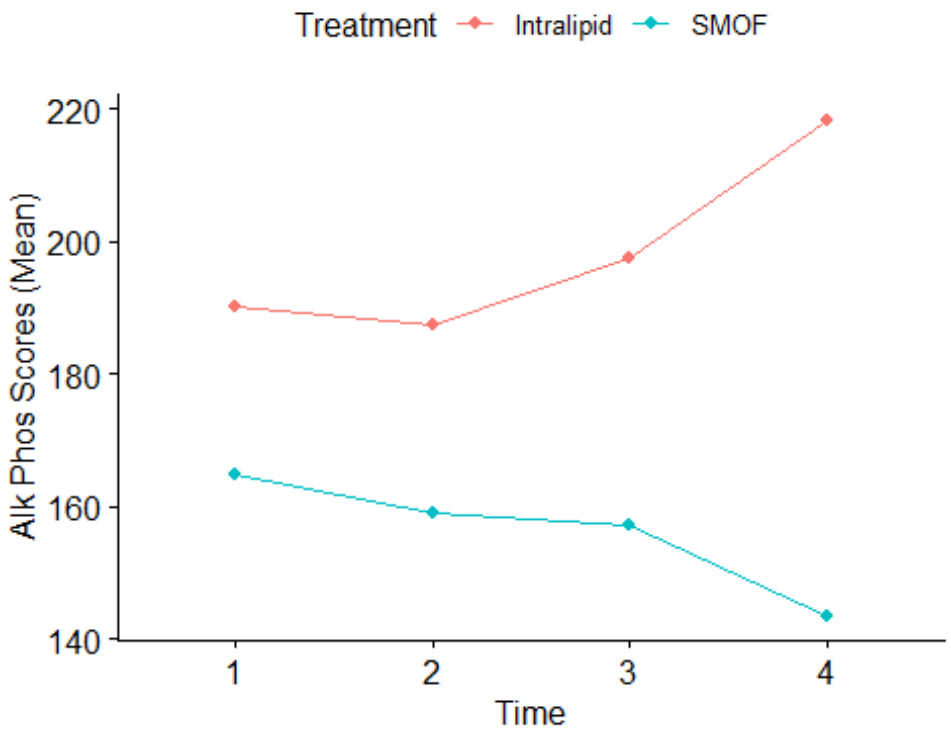
The percentage variations have been obtained in the attached data analytics.

Considering that we were interested in changes in lipid scores over the 4-week intervention stages, we next computed a change score for each of the lipid outcomes, which will account for the individual's starting values within each lipid group at the beginning of the intervention. Initial examinations demonstrated that the change scores were negative for the SMOF subgroup ($M_{Alk.}$ = -21.47, $SD_{Alk.}$ = 70.60, $M_{Ast.}$ = -3.11, $SD_{Ast.}$ = 10.74; $M_{Alt.}$ = -3.64, $SD_{Alt.}$ = 2.32; M_{Total} = -9.41, SD_{Total} = 29.06), while all scores were positive for the Intralipid subgroup ($M_{Alk.}$ = 28.18, $SD_{Alk.}$ = 75.58, $M_{Ast.}$ = 13.27, $SD_{Ast.}$ = 57.01; $M_{Alt.}$ = -13.64, $SD_{Alt.}$ = 61.98; M_{Total} = 18.36, SD_{Total} = 56.21). Paired sample *t*-tests once again showed significant changes in lipid scores for the lipid groups [all *t*s (44) > 1.46, *p*s < .037], as well as the total lipid scores [*t* (44) = 2.70, *p* = .005). To quantify the changes more effectively over the intervention stage, we converted the changes in scores into percentages (subtracting week 4 scores from starting values, dividing by starting values, and multiplying by 100 for a percentage). Calculations revealed that while values for LFTs increased in all the Intralipid values (an increase of 14.82% for ALP- lipids, an increase of 30.50% for AST- lipids, and an increase of 26.71% for ALT lipids). SMOF scores decreased by 12.98% for ALP-lipids, 9.51% for AST, and 10.58% for ALT. On average, total lipid scores decreased by 12.17% in the SMOF subgroup. The changes for the Intralipid subgroup can be found in Figure 2, while changes for the SMOF subgroup can be found in Figure 3. Finally, as a formal check that the order of administration did not influence outcomes, we ran a regression

analysis with an order of administration [0 = received Intralipid first (n = 29), 1 = received SMOFlipid first (n = 16)] as the sole predictor. Results revealed no significant impact of the order of administration on the average Lipid score for the Intralipid subgroup (b = -.11, p = .474), nor for the SMOFlipid subgroup (b = -.06, p = .719). Similar results emerged for all the specific lipids for the Intra subgroup (ALP., AST., ALT.; all | b |s < .13, ps < .377) as well as for the SMOFlipid subgroup (all | b |s < .06, ps < .679), further suggesting that administration order did not impact the significant changes found in the study.

ALP Analysis

Data Visualization + General Summary

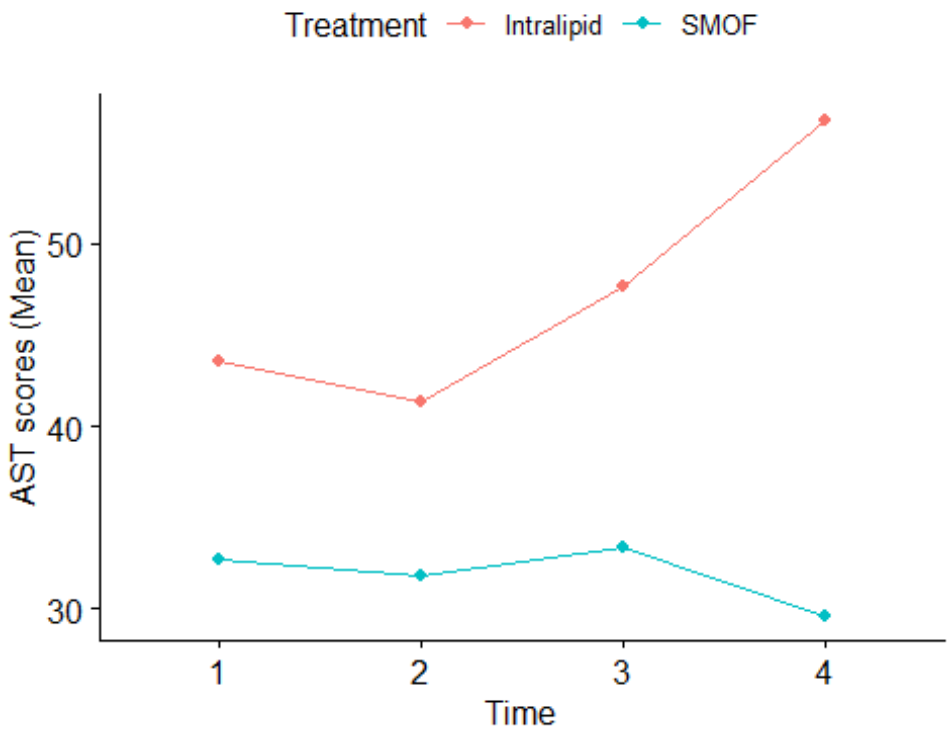


The results demonstrate that there are significant differences in ALP between the two treatment groups at each trial. The Intralipid treatment is shown to have higher ALP scores than the SMOF treatment at each time period. In addition, the trend of ALP. Scores per time are shown to be statistically different

based on the treatment type. ALP scores are shown to gradually increase over each trial for the Intralipid treatment. Whereas ALP scores are shown to gradually decrease over each trial for the SMOFlipid treatment group.

AST scores Analysis

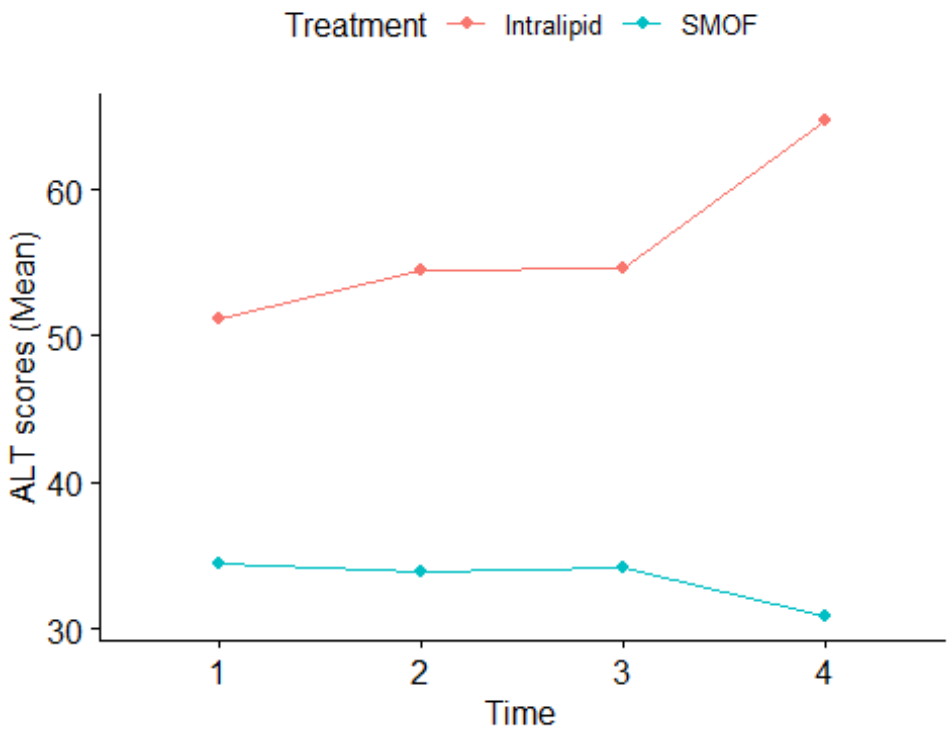
Data Visualization



The results demonstrate that there are significant differences in AST scores between the two lipid emulsion groups overall. The Intralipid group is shown to have higher AST scores than the SMOFlipid group within the overall study. However, despite the visual differences in AST scores trends between the treatment types over time, the differences in trends were not found to be statistically significant.

ALT scores Analysis

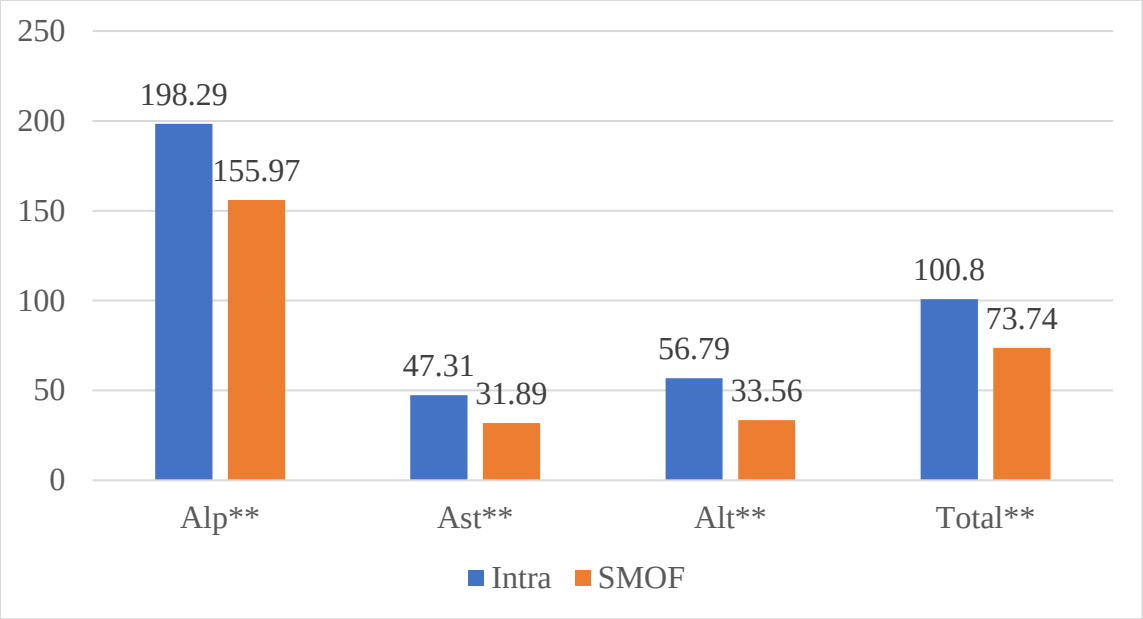
Data Visualization



The results demonstrate that there are significant differences in ALT scores between the two treatment groups overall. The Intralipid group is shown to have higher ALT scores than the SMOFlipid treatment group within the overall analysis. However, despite the visual differences in AST scores trends between the treatment types over time, the differences in trends were not found to be statistically significant.

Figure 1

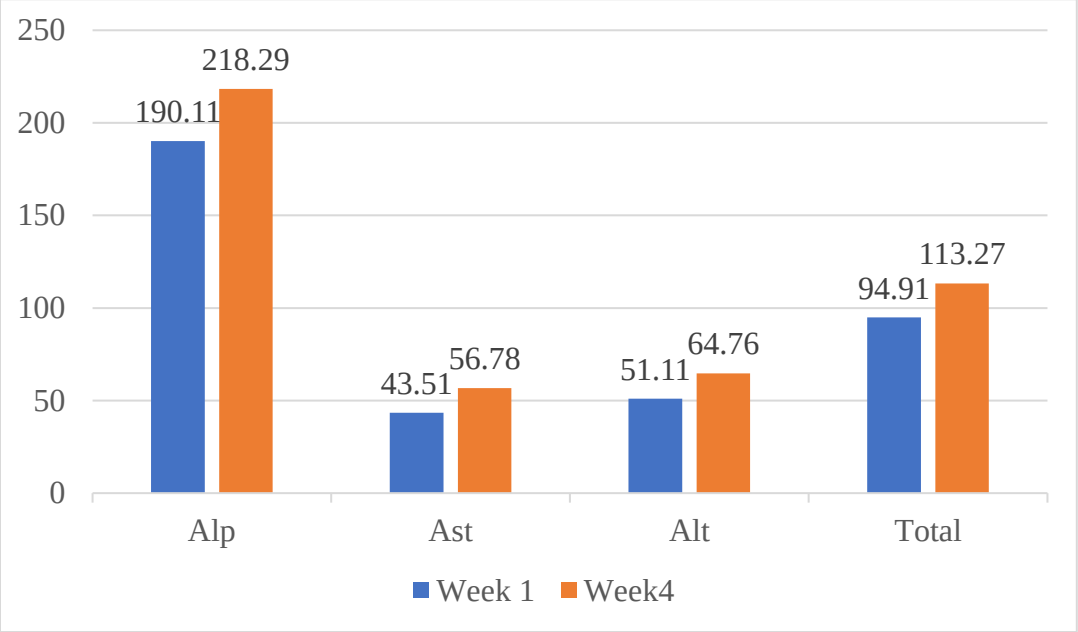
Visual depiction of differences in lipid scores across intervention groups



Note: $N = 45$. ** difference significant at $p < .001$.

Figure 2

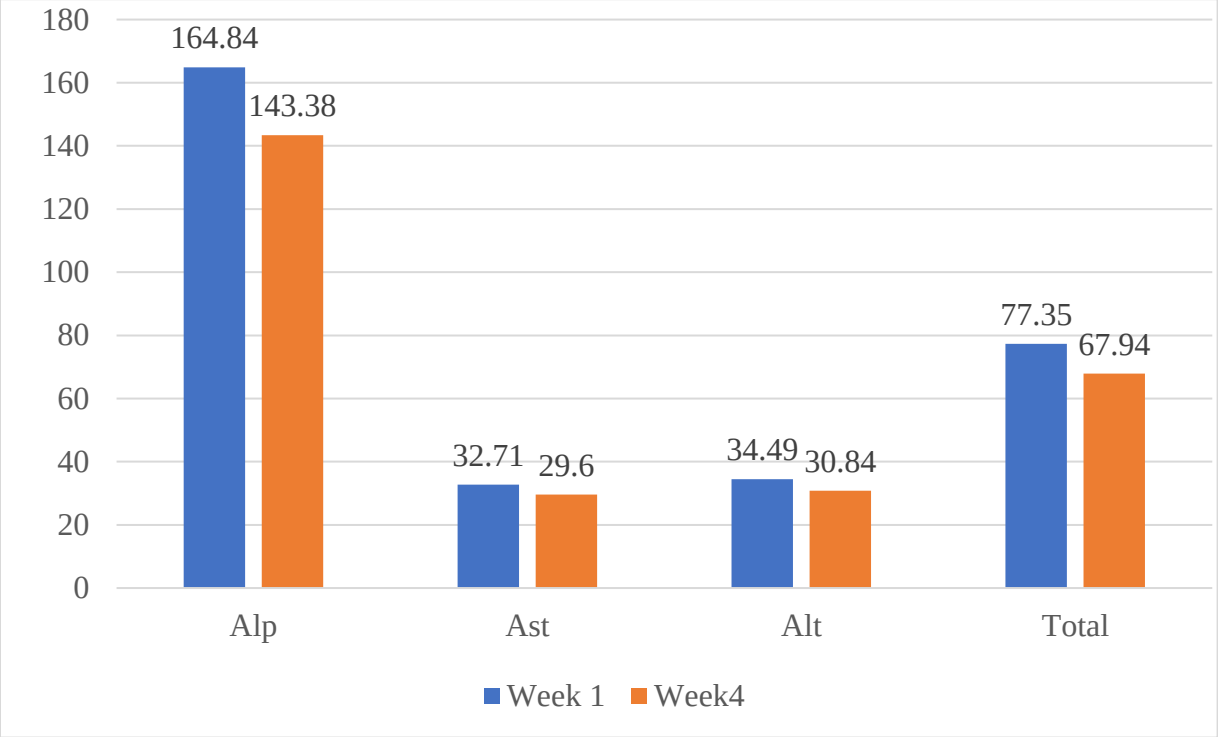
Visual depiction of changes in lipid scores in the Intralipid group



Note: $N = 45$.

Figure 3

Visual depiction of changes in lipid values in the SMOFlipid group



Note: $N = 45$.

Discussion

Summary

The results from the study showed the comparison of the 2 variables, SMOFlipid, and Intralipid. The descriptive statistics for the variables showed that the mean Alkaline phosphate levels were lower with SMOFlipid (161.29) compared to Intralipid (186.62), while the mean AST levels were also lower with SMOFlipid (34.87) compared to Intralipid (43.83). Finally, the mean ALT levels were slightly higher with Intralipid (49.24) compared to SMOFlipid (40.88).

The results indicate confirmation that SMOFlipid is superior to Intralipid in terms of resulting in lower LFTs (ALP, ALT, and AST). The statistical analysis was done using paired t-tests in SPSS and Excel which revealed that for Alkaline Phosphate (ALP,-AST, and ALT, the p-value was less than 0.05, indicating sufficient statistical evidence to affirm the claim that SMOFlipid is superior to Intralipid in terms of resulting in lower LFTs.

This study demonstrates the importance of lipid emulsions in total parenteral nutrition and provides insight into the outcomes of individual patients when switching or choosing between Intralipid and SMOFlipid. Furthermore, the study highlights the advantages of SMOFlipid over Intralipid in terms of lower LFTs. The key findings of this QI project are that there is sufficient statistical evidence to affirm the claim that SMOFlipid is superior to Intralipid in terms of resulting in lower LFTs (ALP and AST) at a 5% level of significance.

The statistical analysis using paired t-tests and Excel provides a reliable method to compare the outcomes of the two lipid emulsions in total parenteral nutrition among home infusion patients. One of the strengths of this project is that the statistical analysis was conducted using appropriate tests and techniques, and the results were interpreted accurately. This was through the use of paired t-tests to compare the outcomes of Intralipid and SMOFlipid and the

use of statistical software to analyze the data. Additionally, percentage changes were also obtained to provide additional insight into the findings. The results of this project are relevant to the rationale and specific aims of the project, as it provides evidence of the superiority of SMOFlipid over Intralipid in terms of lower LFTs for home infusion patients receiving total parenteral nutrition.

Interpretation

The intervention studied in this project was the use of lipid emulsions in total parenteral nutrition among home infusion patients. The primary outcome measure studied was the levels of three liver function tests (LFTs): ALP, AST, and ALT. A paired t-test was used to compare the outcomes of using SMOFlipid and Intralipid in terms of resulting in lower LFTs.

This project has the potential to positively impact people and systems, predominantly Penn Home Infusion Therapy. The results of this study suggest that SMOFlipid is more effective than Intralipid in terms of resulting in lower LFTs. This could lead to improved patient outcomes, as lower LFTs can result in better health outcomes for home infusion patients. It is recommended that home infusion patients should be given SMOFlipid as the preferred lipid emulsion for total parenteral nutrition when appropriate and in the absence of an allergy to a SMOFlipid component. Additionally, the use of SMOFlipid could lead to cost savings for healthcare systems, as the cost of the lipid emulsion is now lower than that of Intralipid.

The results of this project are consistent with previous research and are in line with the anticipated outcomes. To evaluate the effectiveness of lipid emulsions, two studies are considered. The first study by McGuigan (2021) looked at the effect of a single intravenous lipid emulsion on liver function tests in post-operative home infusion patients. They studied 78

patients who were divided into four groups according to the type of lipid emulsion they received during their infusion: SMOFlipid, Intralipid, MCT/LCT, and intact triglyceride. The study found that SMOFlipid resulted in lower liver function test (LFT) levels, especially those related to ALP and AST, compared to Intralipid.

The second study by Klek et al. (2021) analyzed the effect of a single intravenous lipid emulsion on LFTs in parenteral nutrition patients with chronic diseases in a long-term hospital setting. They studied 59 patients who were divided into three groups according to the type of lipid emulsion they received during their infusion: SMOFlipid, Intralipid, and MCT/LCT. The study found that SMOFlipid was more effective than both Intralipid and MCT/LCT in terms of resulting in lower LFT levels, specifically in the case of ALP and AST.

These studies have provided evidence that SMOFlipid is more effective than Intralipid in terms of resulting in lower LFTs, especially in the case of ALP and AST. This suggests that SMOFlipid is the preferred choice for home infusion TPN patients as it is associated with lower LFTs. It should, however, be noted that both studies are limited to examining only two types of lipids and their effects on liver function tests. Further research is needed to examine additional types of lipids and other variables that may influence the effectiveness of different lipids, such as patient age, disease severity, and duration of infusion therapy.

However, it is important to note that the results of this project may not be applicable to all home infusion patients. The results may differ depending on the individual patient's context, such as age, gender, and pre-existing conditions. Additionally, the results may vary depending on the specific type of lipid emulsion used, as there are a number of different lipid emulsions now available from different manufacturers.

When analyzing the costs and strategic trade-offs, including opportunity costs, the use of SMOFlipid may lead to cost savings for the healthcare system/PHIT, as the cost of the lipid emulsion is lower than that of Intralipid. Additionally, the use of SMOFlipid may result in improved patient outcomes, as lower LFTs can result in better health outcomes for home infusion patients. However, there may be some trade-offs to consider when deciding to use SMOFlipid. For example, SMOFlipid may not be as effective as Intralipid in terms of resulting in lower LFTs in certain patients. Additionally, there may be opportunity costs associated with using SMOFlipid, as the use of Intralipid may result in better patient outcomes in some cases when SMOFlipid is not available or appropriate.

Limitations

Despite the fact that the quality improvement project was conducted in a methodological and rigorous way, there are certain limitations to the generalizability of the work. Firstly, the project was conducted on a relatively small sample size of forty-five home infusion patients, and thus, the results may not be applicable to a larger population. In addition to the limitations of the generalizability of the work, factors that might have limited the internal validity of the project include confounding, bias, and imprecision in the design, methods, measurement, or analysis. For example, the project did not consider other factors that might influence the LFTs such as diet, lifestyle, and medications. Additionally, the project did not consider the possible interactions between the two lipid emulsions, which could have affected the results.

To minimize and adjust for the limitations, the project was conducted using as rigorous a methodology as possible. The sample size was kept as small as possible to ensure that the results were not influenced by outliers. Furthermore, the project was conducted over a relatively short duration of time to ensure that the results were not affected by long-term changes. Additionally,

the project was conducted in a single location to ensure that the results were applicable to the population in that specific area. The project used SPSS and Excel to perform statistical analysis and obtain descriptive statistics. Along with utilizing paired t-tests to compare the outcomes of Lipid Emulsions in Total Parenteral Nutrition among Home Infusion patients. This method of analysis helps to reduce the impact of confounding factors and bias in the data.

Furthermore, efforts were made to ensure that the participants were representative of the target population and were not selected based on any preconceived notion of the results. Additionally, the project took into consideration the changes in the LFTs of individuals who switched from Intralipid to SMOFlipid and vice versa.

Conclusion

In conclusion, this quality improvement study has examined the outcomes of lipid emulsions in total parenteral nutrition among home infusion patients. The results of the project suggest that SMOFlipid is superior to Intralipid in terms of resulting in lower LFTs (ALP, ALT, and AST) at a 5% level of significance. This research is useful in determining the best lipid emulsion to use for parenteral nutrition among home infusion patients. The findings of this quality improvement project are very useful as they can be sustained by carrying out further studies with larger sample sizes to further validate the results. Moreover, the findings of this project can be applied to other contexts, such as hospital settings, to determine the best lipid emulsions for parenteral nutrition. The implications for practice are that healthcare practitioners should take into consideration the findings of this research and recommend SMOFlipid to home infusion patients for parenteral nutrition. Additionally, the use of SMOFlipid could lead to cost savings for healthcare systems, as the cost of the lipid emulsion is lower than that of Intralipid. However, it is important to consider the trade-offs and opportunity costs associated with the use

of SMOFlipid before planning, as the wholesale price is fluid and changes with fluctuations in the price of its components, i.e., eggs, olive oil, etc.

Further research should be conducted to determine if there are any other factors that can impact the efficacy of lipid emulsions in terms of reducing LFTs. It is also important to note that the results of this quality improvement project are only applicable to home infusion patients and may not be applicable to other patient populations. Moreover, one should note that there were no other observable trends comparing how the LFTs changed from individuals who switched from Intralipid to SMOFlipid and vice versa. The percentage changes were random and varied from one individual to another. Therefore, it is important to take individual patient characteristics into consideration when making decisions regarding lipid emulsions in total parenteral nutrition. It is important to note that statistical significance does not necessarily imply clinical significance. Therefore, it is essential to consider the practical significance of the findings before making any clinical decisions. Additionally, it is recommended to consult with a healthcare professional who specializes in clinical nutrition before making any changes to a patient's treatment plan regarding TPN and lipid emulsions.

Suggested next steps include researching the effects of different lipid emulsions in different patient populations, such as those with diabetes or other chronic illnesses. Additionally, research should also be conducted to determine the effects of different lipid emulsions in long-term parenteral nutrition.

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Appendix A: Paired t-tests

t-Test: Paired Two Sample for Means - ALP

	Intralipid	*SMOF*	
Mean	198.2944	155.9722	
Variance	26856.03	19819.47	ALP
Observations	45	45	
Pearson Correlation	0.961		
Hypothesized Mean Difference	0		
df	44		
t Stat	5.86780		
P(T<=t) one-tail	< 0.001		
t Critical one-tail	1.68023		
P(T<=t) two-tail	< .001		
t Critical two-tail	2.015368		

t-Test: Paired Two Sample for Means - AST

	Intralipid	*SMOF*
Mean	47.3111	31.8889
Variance	1839.097	1136.939
Observations	45	45
Pearson Correlation	0.813	
Hypothesized Mean Difference	0	
df	44	
t Stat	4.13821	
P(T<=t) one-tail	< .001	
t Critical one-tail	1.68023	
P(T<=t) two-tail	< .001	
t Critical two-tail	2.015368	

t-Test: Paired Two Sample for Means - ALT

	Intralipid	*SMOF*	
Mean	56.7944	33.3556	
Variance	3798.603	1841.428	ALT
Observations	45	45	
Pearson Correlation	0.792		
Hypothesized Mean Difference	0		
df	44		
t Stat	4.13052		
P(T<=t) one-tail	< .001		
t Critical one-tail	1.68023		
P(T<=t) two-tail	< .001		
t Critical two-tail	2.015368		

Appendix B: SMOF to Intralipid

Average Changes for the Four Weeks

Intralipid	SMOFlipid	% Change
758.50	831.50	9.62
86.50	113.25	30.92
69.75	86.50	24.01
154.00	129.00	-16.23
27.50	14.00	-49.09
23.00	15.75	-31.52
422.75	473.00	11.89
50.75	54.00	6.40
96.00	92.25	-3.91
112.50	100.00	-11.11
30.75	14.00	-54.47
23.75	15.33	-35.44
108.00	85.00	-21.30
79.50	34.50	-56.60
214.75	64.50	-69.97
99.75	263.75	164.41
25.25	129.25	411.88
19.50	129.75	565.38
77.25	72.25	-6.47
17.75	17.75	0.00
6.50	6.50	0.00
77.00	76.00	-1.30
17.50	21.50	22.86
18.00	25.25	40.28

105.75	128.33	21.36
26.75	52.67	96.88
28.75	121.33	322.03
83.75	84.00	0.30
25.25	28.00	10.89
23.50	21.25	-9.57
206.75	198.50	-3.99
52.50	38.00	-27.62
74.25	55.75	-24.92
58.00	61.25	5.60
21.50	23.75	10.47
20.75	19.00	-8.43
87.00	87.50	0.57
29.50	40.75	38.14
36.00	40.50	12.50
51.50	57.00	10.68
25.00	24.25	-3.00
21.50	24.75	15.12
28.50	34.00	19.30
20.75	43.00	107.23
68.00	53.33	-21.57
14.67	15.33	4.55
10.00	11.00	10.00
85.00	118.75	39.71
20.75	23.25	12.05
21.75	18.50	-14.94
396.25	332.75	-16.03
50.75	39.00	-23.15
65.50	48.00	-26.72
63.25	65.50	3.56
26.25	22.00	-16.19
33.25	26.75	-19.55
95.50	104.25	9.16
22.00	24.50	11.36
13.75	9.25	-32.73
128.25	115.50	-9.94
17.75	17.00	-4.23
8.75	7.75	-11.43
133.75	174.50	30.47

34.00	37.00	8.82
20.75	83.75	303.61
95.50	83.75	-12.30
12.75	10.25	-19.61
7.50	4.25	-43.33

Appendix C: Intralipid to SMOF

Average Changes for the Four Weeks

Intralipid	SMOFlipid	% Change
219.50	160.25	-26.99
29.25	29.75	1.71
38.00	14.25	-62.50
47.75	69.00	44.50
17.75	21.25	19.72
28.75	32.25	12.17
165.75	162.00	-2.26
21.50	24.25	12.79
16.75	23.75	41.79
77.75	68.50	-11.90
18.75	38.00	102.67
13.00	35.50	173.08
100.00	151.50	51.50
14.00	13.75	-1.79
15.33	11.50	-25.00
95.25	81.00	-14.96
30.50	22.50	-26.23
24.50	10.75	-56.12
140.75	128.50	-8.70
27.25	21.50	-21.10
26.50	15.00	-43.40
252.50	158.00	-37.43
89.50	48.50	-45.81

104.00	40.00	-61.54
638.25	622.75	-2.43
38.75	43.25	11.61
39.25	50.75	29.30
237.50	197.50	-16.84
24.00	19.75	-17.71
16.75	11.50	-31.34
285.75	122.00	-57.31
117.50	28.25	-75.96
165.25	46.50	-71.86
183.75	126.50	-31.16
28.00	15.25	-45.54
26.75	14.00	-47.66
278.75	232.50	-16.59
36.00	22.75	-36.81
51.50	24.00	-53.40
110.67	80.50	-27.26
35.33	25.50	-27.83
41.67	18.75	-55.00
128.33	78.25	-39.03
52.67	25.00	-52.53
121.33	42.25	-65.18
208.50	203.00	-2.64
36.25	42.50	17.24
51.50	65.50	27.18
181.25	114.25	-36.97
17.00	15.00	-11.76
19.50	13.25	-32.05
187.00	301.00	60.96
68.50	72.00	5.11
62.50	113.25	81.20
110.00	106.00	-3.64
34.67	18.00	-48.08
50.33	28.00	-44.37
63.00	63.75	1.19
27.00	15.50	-42.59
20.00	14.75	-26.25
53.33	64.75	21.41
15.33	21.25	38.59

11.00	24.00	118.18
274.25	226.75	-17.32
53.25	37.75	-29.11
70.50	57.00	-19.15
141.25	154.00	9.03
93.75	25.00	-73.33
111.50	48.75	-56.28
122.75	96.25	-21.59
21.25	20.50	-3.53
13.00	15.75	21.15
256.75	277.50	8.08
236.25	251.75	6.56
287.00	299.75	4.44
395.25	396.25	0.25
48.50	50.75	4.64
91.00	65.50	-28.02
332.75	297.25	-10.67
39.00	36.50	-6.41
48.00	64.50	34.38
93.00	134.25	44.35
22.25	25.00	12.36
15.25	14.00	-8.20
100.25	96.25	-3.99
16.00	15.50	-3.13
7.50	7.50	0.00
159.50	119.50	-25.08
33.00	28.00	-15.15
16.50	13.25	-19.70
223.75	230.00	2.79
44.00	58.75	33.52
27.25	60.25	121.10
97.00	118.67	22.34
35.00	12.33	-64.76
39.25	17.00	-56.69