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Measurement of StO2 Prehospital and Lactate Levels on the Arrival at the Hospital: Observational Study in Mountain Traumatology

Philippe Mahiou, Dominique Savary & Jacques Duranteau

University Hospital of Grenoble Alpes

ABSTRACT

Introduction: Hypovolemia is a major complication of trauma patients, leading, if not treated rapidly, to tissue and organ hypoperfusion and the development of multiple organ failure. During the out-of-hospital management of trauma patients, it is recommended to maintain the blood pressure the first time with the fluid administration and if it is not sufficient the second time by a vasopressor.

The aim of these treatments is to avoid microcirculation alteration with a deficit of tissue perfusion and oxygen delivery to vital organs. In trauma patients, peripheral muscle tissue oxygen saturation (StO2) measured by near-infrared spectroscopy (NIRS) was shown to be more reliable than systemic hemodynamic variables as an index of severity of traumatic shock.

Keywords: prehospital microvascular management - StO2 - NIRS - lactate - mountain traumatology.

Classification: NLM Code: WO 700

Language: English

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Measurement of StO2 Prehospital and Lactate Levels on the Arrival at the Hospital: Observational Study in Mountain Traumatology

Philippe Mahiou[α], Dominique Savary[σ] & Jacques Duranteau[ρ]

ABSTRACT

Introduction: Hypovolemia is a major complication of trauma patients, leading, if not treated rapidly, to tissue and organ hypoperfusion and the development of multiple organ failure. During the out-of-hospital management of trauma patients, it is recommended to maintain the blood pressure the first time with the fluid administration and if it is not sufficient the second time by a vasopressor.

The aim of these treatments is to avoid microcirculation alteration with a deficit of tissue perfusion and oxygen delivery to vital organs. In trauma patients, peripheral muscle tissue oxygen saturation (StO2) measured by near-infrared spectroscopy (NIRS) was shown to be more reliable than systemic hemodynamic variables as an index of severity of traumatic shock.

The objective of this prospective study was to compare hemodynamic variables and the lactate values with the regional tissue oxygenation saturation monitoring (StO2) measured by near-infrared spectroscopy in the prehospital management of mountain trauma patients.

Material and Methods: This prospective observational cohort study was performed during 13 months. Helicopter emergency teams enrolled mountain trauma patients. At the arrival of the emergency team, the control of an external hemorrhage was first performed. The fluid loading was recommended first with crystalloids (isotonic saline 0,9 %) and after if it was not sufficient, norepinephrine is proposed if the object blood pressure was not reached after the infusion of one liter and half of crystalloids.

The objective of systolic blood pressure (SBP) was 80-90 mmHg in patients with no head injury and 120 mmHg in case of severe head injury. For each patient, the following data were recorded: patient's demographics, mechanism and altitude of the trauma, the suspected injuries and the severity of trauma, vital signs as GCS, heart rate (HR), non invasive systolic and diastolic arterial pressure, oxygen saturation with a pulse oximeter and epitympanic temperature. The MGAP score (Mechanism of injury, GCS, Age, systolic arterial Pressure) was calculated. Regional tissue oxygen saturation (StO2) was measured using near-infrared spectroscopy (NIRS) after securing the StO2 probe to the thenar eminence of the hand. The venous blood lactate level was collected while the venous catheter was inserted during the prehospital management (lactate T0) and at the hospital admission to Emergency Medical Service (lactate Adm). The volumes of intravenous fluids and the vasopressor doses, if associated with volume expansion, administered during the prehospital management were recorded.

Results: During 13 months, 30 mountain trauma patients were prospectively enrolled in the helicopter mountain rescue units. The victims of an accident were often skiing in 57%, paragliding in 13% and snowshoeing in 10%. The StO2 measure was achieved in 96 % of cases whatever was the outside temperature (even if < 5 °C) with low body temperature patients (mild hypothermia 32-35 °C in 20%, severe hypothermia 28-32 °C in 3 % of cases). In these conditions, the SpO2 value could only be obtained in 16,6 %. The volume expansion was performed with isotonic saline in 48% of patients, and 15% needed isotonic saline and a continuous infusion of norepinephrine. According to the Northern French Alps Emergency Network Classification,

43% of trauma patients were stabilized before the hospital admission but in 7% of cases the outdoor resuscitation didn't permit the patient's stabilization before the hospital arrival.

We found a significant correlation of the initial StO2 value (StO2 T0) to the blood lactate level collected at hospital admission (lactate Adm) (R^2= 0,40; p = 0,0003). The StO2 T0 value permits to predict a lactate level > 2 mmol/l at the hospital admission (AUC= 0,86, threshold value of StO2 < 73,5%) with a good sensitivity and specificity.

Discussion: The results of our study demonstrate that NIRS derived StO2 is a non-invasive measure able to predict tissue hypoperfusion and feasible in the outdoor setting whatever the outside and the patient body temperature. Alterations in regional tissue perfusion often precede global signs of shock therefore StO2 may represent an important screening tool for early identifying trauma patients who require an intensive and preventive resuscitation. Thus, monitoring tissue oxygenation provides information about the state of microcirculation.

In hypovolemic patients, the decrease of StO2 (thenar eminence) is due to the decrease of the muscle blood flow because of centralization of blood flow to vital organs. Peripheral tissues are the first to reflect hypoperfusion in shock. Poor peripheral perfusion may therefore be considered as an early predictor of tissue hypoperfusion and ongoing shock. Tissue hypoperfusion is a recognized pathophysiological process leading to multiple organ dysfunction and death. In trauma patients with severe shock, StO2 was lower than in milder grades of shock or in normal individuals. StO2 within one hour of admission was lower in trauma patients who developed multiorgan dysfunction (MODS) or died and so a low StO2 was a strong predictor of MODS and death. In hypovolemic trauma patients, low StO2 predicts adverse outcomes.

Conclusion: Prehospital measurement of StO2 is feasible in mountain trauma patients and may become a useful parameter of the severity of injury and in the identification of tissue hypoperfusion. StO2 monitoring appears feasible and reliable even when the other routine parameters such as SpO2, HR and NIBP are inconsistent or not possible to measure. In our study, the StO2 T0 value was permitted to predict a lactate level superior to 2 mmol/l at the hospital admission, which was in accordance with the results of several previous studies. We believe that NIRS-determined StO2 may become a useful parameter of trauma patient monitoring in the prehospital setting, in particular in austere environments and during air transport and in the future, StO2 value could even become integrated into trauma scores.

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I. INTRODUCTION

Hypovolemia is a significant complication of trauma patients, leading, if not treated rapidly, to tissue and organ hypoperfusion and the development of multiple organ failures. So, during the out-of-hospital management of trauma patients, it is recommended to maintain the blood pressure using first fluid administration and, if not sufficient, second a vasopressor support (norepinephrine). These interventions should be continued until the correction of hemodynamic parameters: static (blood pressure, heart rate, cardiac index) and dynamic parameters (pulse pressure variation, stroke volume) (1). The real aim of these interventions is to avoid microvascular alteration with a deficit of tissue perfusion and oxygen delivery to vital

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organs, well documented in patients with hemorrhagic shock.

Many studies highlight the predictive value of microvascular perfusion and the correlation of microvascular hypoperfusion with the development of multiple organ dysfunction syndrome and mortality (2)(3). Microcirculation (diameter of vessels < 100 μm) is currently considered as a vital organ, which is responsible for tissue oxygen supply (4). In a study, an early increase in microcirculatory perfusion was associated with reduced multi-organ failure and that independently of the systemic hemodynamic variables that remained unchanged (5). In the case of trauma patients, peripheral muscle tissue oxygen saturation (StO2) determined by near-infrared spectroscopy (NIRS) was shown to be more reliable than systemic hemodynamic variables as an index of severity of traumatic shock (6) (7) (8).

The objective of our prospective study was to compare hemodynamic variables and venous blood lactate values with the regional tissue oxygenation saturation (StO2) using near-infrared spectroscopy in the prehospital management of mountain trauma patients.

II. MATERIAL AND METHODS

This prospective observational cohort study was performed for 13 months. Helicopter emergency teams enrolled mountain trauma patients. We excluded from our study: Patients dead at emergency team arrival, patients with Glasgow Coma Scale<4, patients with bilateral fractures of the upper extremities or with bilateral thenar eminence damage, pregnant women and patients < 18 years of age.

2.1 Interventions

First and if necessary, at the arrival of the helicopter emergency team, the control of an external hemorrhage was first performed if necessary. A peripheral vein catheter was inserted. The fluid loading was recommended first intention with crystalloids (isotonic saline 0,9 %).

In several cases, if not sufficient norepinephrine is proposed if the object blood pressure is not

reached after the infusion of one liter and half of crystalloids. The objective of systolic blood pressure (SBP) was: 1/80-90 mmHg in patients with no head injury and 2/ 120 mmHg in case of severe head injury. If the objective of SBP wasn't reached by fluid loading alone, a vasopressor support (norepinephrine) was initiated (9)(10).

2.2 Data collection and StO2 measurements

For each patient, the following data were recorded: the patient's demographics, the mechanism and the altitude of the trauma, the suspected injuries and the severity of trauma according to the trauma grading in the Northern French Alps Emergency Network (11) (Table 1), the vital signs as GCS, heart rate (HR), non invasive arterial pressure (systolic and diastolic), oxygen saturation with a pulse oximeter and epitympanic temperature. The MGAP score (*Mechanism of injury*, *GCS*, *Age, systolic arterial Pressure*) was calculated (12).

Regional tissue oxygen saturation (StO2) was measured using near-infrared spectroscopy (NIRS) after securing the StO2 probe to the thenar eminence of the hand (Model TM InSpectra StO2 SpotCheck, Hutchinson Technology, MN, USA). StO2 was measured at the arrival of the emergency team and after that every 10 minutes until the arrival at the hospital.

The venous blood lactate level was collected while the venous catheter was inserted during the prehospital management (lactate T0) and at the hospital admission to Emergency Medical Service (lactate Adm).

The volumes of intravenous fluids and the vasopressor doses, if associated with volume expansion, administered during the prehospital management were recorded.

2.3 Statistical analysis

Data are presented as mean value ± standard deviation, and the percentage. The predictive value on the outcome of the slope was calculated using a receiver operator characteristic (ROC) curve, the area under the curve (AUC) was computed.

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III.　RESULTS

For 13 months, 30 mountain trauma patients were prospectively enrolled in two helicopter mountain rescue units. Twenty-one patients were males and nine were females, from 16 to 77 years (mean age 43 ± 20 years), victims of an accident of skiing in 57% of paragliding in 13% and of snowshoeing in 10% (Figure 1). The median altitude of the rescue interventions was 1290 ± 639 meters. The StO2 measure was achieved in 96 % of cases whatever was the outside temperature (even if < 5 °C) and with low bodies patients' temperatures (mild hypothermia 32-35 °C in 20%, severe hypothermia 28-32 °C in 3 % of cases). In these hypothermia conditions, the SpO2 value could only be obtained at 16,6 % (Table 2). The volume expansion was performed with isotonic saline in 48% of patients, and 15% needed isotonic saline and a continuous norepinephrine infusion.

According to the Northern French Alps Emergency Network Classification (Figure 2), 43% of trauma patients were stabilized before the hospital admission. In 7% of cases the outdoor resuscitation didn't permit the patient's stabilization before the hospital arrival.

In two patients the MGAP score (Figure 3) was high (11 and 14) predicting an increased risk of adverse clinical outcome (mean mortality of 46%).

The initial StO2 measure was available in these 2 cases (StO2 T0 values of 64% and 66% respectively) but the SpO2 couldn't be obtained.

We found a significant correlation of the initial StO2 value (StO2 T0) to the blood lactate level collected at hospital admission (lactate Adm) (R^2= 0,40; p = 0,0003). The StO2 T0 value permits to predict a lactate level > 2 mmol/l at the hospital admission (AUC= 0,86, threshold value of StO2 < 73,5%) with a good sensitivity and specificity (Figures 4a and 4b).

IV.　DISCUSSION

The results of our study demonstrate that NIRS derived StO2 is a non-invasive measure able to predict tissue hypoperfusion and is feasible in the outdoor setting whatever the outside and the body temperature. Regional alteration tissue perfusion often precedes global indications of shock therefore StO2 may represent an important screening tool for early identifying trauma patients who require intensive resuscitation.

Tissue oxygenation may reflect changes in microcirculation, which is an important target in trauma patients. Alterations of microcirculation are documented in hemorrhage and critical illness and they are in relation to tissue oxygenation.

Thus, monitoring tissue oxygenation may provide information about the state of microcirculation. In hypovolemic patients, the decrease of thenar eminence StO2 is due to the reduction of the muscle blood flow because of the centralization of blood flow to vital organs. Peripheral tissues are the first to reflect hypoperfusion in shock. Poor peripheral perfusion may therefore be considered as an early predictor of tissue hypoperfusion and ongoing shock. Tissue hypoperfusion is a recognized pathophysiological process leading to multiple organ dysfunction and death.

We chose the thenar eminence as an NIRS-derived StO2 monitoring site for several reasons: the thenar eminence is easily accessible despite all technical difficulties of rescue in the hostile mountain environment and the relatively thin fat tissue over the muscle is an advantage in minimizing variability. We found this non-invasive monitoring to be feasible in prehospital trauma patients because NIRS technology is not dependent on the identification of pulsatile flow and a previous animal study showed no significant effects of body temperature on StO2 values (8). The monitoring of pulse oximetry (SpO2) often failed and other routine parameters such as heart rate (HR) and non-invasive blood pressure (NIBP) have often spurious readings in the prehospital setting, even more in mountain conditions and during air transport.

A study performed in intensive care patients with increased blood lactate levels during 8 hours of resuscitation showed that half had low StO2 (<70%) on admission. But there was no difference in systemic circulatory variables between patients with common and average StO2.

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Patients who retained low StO2 levels despite initial resuscitation had significantly worse outcomes than patients with average StO2 values.

Common StO2 values were only related to abnormalities of peripheral tissue perfusion (regional hemodynamics) but not of central organs (13). In trauma patients with severe shock, StO2 was lower than in milder grades of shock or in normal individuals (14)(15). StO2 within one hour of admission was more down in trauma patients who developed multiorgan dysfunction (MODS) or died and low StO2 was a strong predictor of MODS and death(16)(17). The lowest StO2 in trauma patients is as good as the lowest systolic blood pressure at identifying severe shock (14)(15). In hypovolemic trauma patients, low StO2 predicts adverse outcomes.

V. CONCLUSION

Prehospital measurement of StO2 is feasible in mountain trauma patients and may become a valuable parameter of the severity of the injury and identifying tissue hypoperfusion. StO2 monitoring appears feasible and reliable even when the other routine parameters such as SpO2, HR and NIBP are inconsistent or impossible to measure. In our study, the StO2 T0 value permitted us to predict a lactate level superior to 2 mmol/l at the hospital admission, which was following the results of several previous studies.

We believe that NIRS-determined StO2 may become a helpful parameter of trauma patient monitoring in the prehospital setting, in particular in austere environments and during air transport and in the future, StO2 value could even become integrated into trauma scores. However, other more extensive studies would be necessary to confirm these findings. Perhaps in the future, it would be possible to include the StO2 value, as an additional and reliable index into the four descriptive stages of the ATLS blood loss (18). In disaster medicine, it would even be possible to use it as additional criteria of quality and performance.
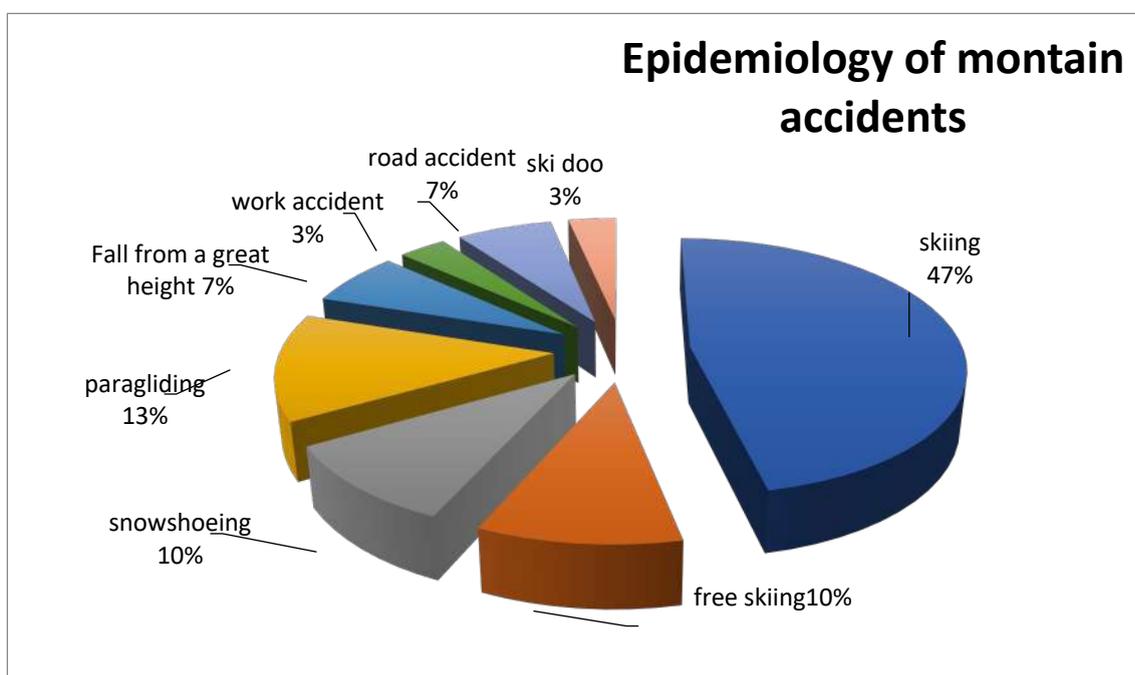
Figure 1: The Mechanisms of Trauma

Table 1: Trauma Grade in the Northern French Alps Emergency Network

Grade A: Unstable Patient

SBP <90 mmHg despite the prehospital resuscitation
Prehospital transfusion
Respiratory distress and/or mechanical ventilation difficult SpO2 <90%

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Grade B: Patient stabilized

Stabilized respiratory distress with SpO2 ≥90%
hypotension corrected
Head trauma with Glasgow Coma Score <13 or motor GCS <5
Penetrating trauma of the head, neck, thorax, abdomen and above the elbows or knees
Flail chest
Amputation or crushing degloving members
Suspicion of severe trauma pelvis
 Suspicion of spinal cord injury

Grade C: Stable Patient

Fall> 6 meters
Patient traumatized victim of ejection, projection, crushing and / or blast
Deceased patient and / or severe trauma in the same accident vehicle
Patient victim of a high kinetic accident at the discretion of the prehospital team
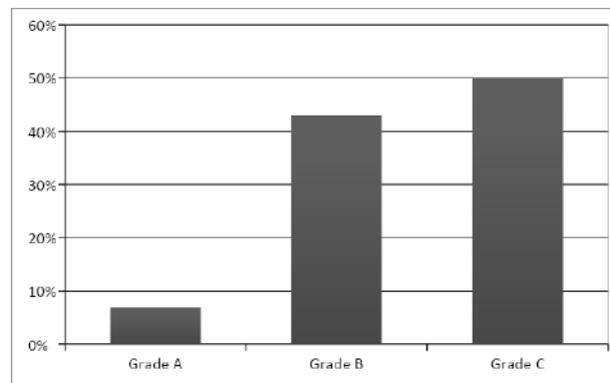
Figure 2: Trauma Grade in the Northern French Alps Emergency Network

Table 2: Comparison Reliable SpO2 Measurement Versus StO2 with Time

Time	SpO2	StO2
T0	16%	96%
T 10 minutes	26%	100%
T 20 minutes	46%	96%
T 30 minutes	66%	96%

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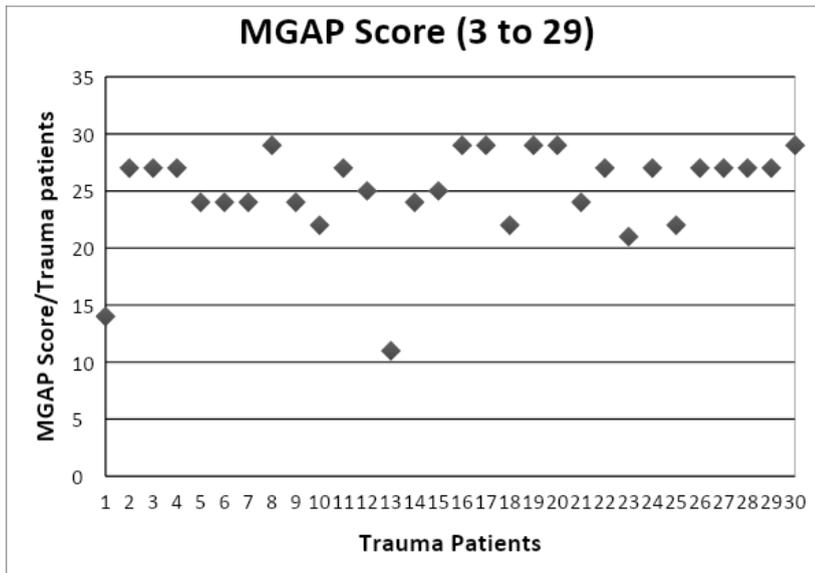
Figure 3: MGAP Score

Figure 4a

Figure 4b

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9. Spahn DR, Cerny V, Coats TJ, Duranteau J, Fernandez-Mondejar E, Gordini G, Stahel PF, Hunt BJ, Komadina R, Neugebauer E, Ozier Y, Riddez L, Schultz A, Vincent JL, Rossai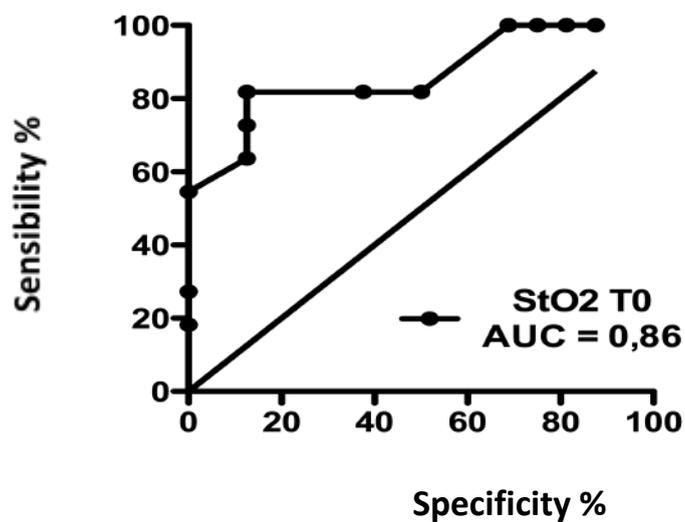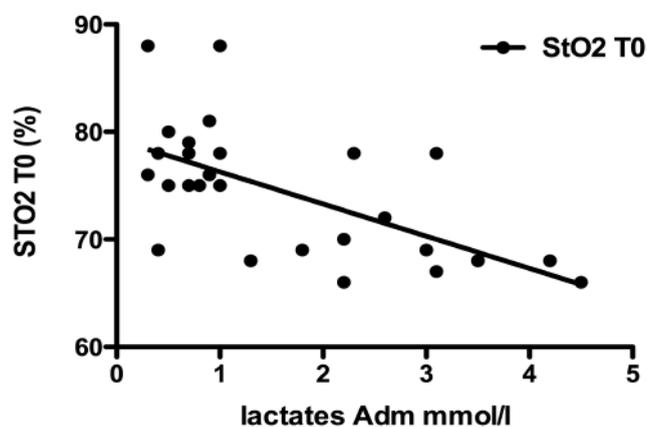nt R, (2016) The European guideline on management of major bleeding and coagulopathy following trauma : fourth edition. Crit Care 20:100.

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Management of a Solid Pseudopapillary Tumor of the Pancreas in a Country with Limited Resources: About a Case

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I. INTRODUCTION

Solid pseudopapillary tumor of the pancreas is a relatively rare tumor, most often found in young women[1,2]. In general, it is a tumor with a low potential for malignancy [3.4]. It is a tumor with clinical polymorphism. These tumors are now recognized with increased frequency thanks to the progress and improvement of imaging techniques. We report a case of pseudo-papillary tumor of the pancreas, which was treated by pancreatic enucleation, in a 19-year-old young woman seen at the Joseph Ravoahangy Andrianavalona University Hospital of Antananarivo (CHU-JRA). Our objective was to discuss therapeutic management compared to the literature.

II. OBSERVATION

Young 19-year-old woman, with no family history of neoplastic presenting with heaviness-type epigastric pain, transfixing, intense, without calming factors or triggering factors, evolving for a year before her admission, worsening, becoming more accentuated and sometimes associated with vomiting for two weeks. She was in good general condition, afebrile. Palpation of the abdomen showed a bulky, firm, rounded, well-defined epigastric mass, mobile in relation to the deep plane, and painful on palpation. The lymph node areas were accessible. Physical examinations revealed lipaemia 1.4 times normal, neutrophil-predominant hyperleukocytosis, AST 1.3 times normal, GGT 1.1 times typical, total bilirubin elevated three times everyday, and bilirubin conjugated at 1.8 times average, the other biological tests were standard (CA 19-9, fasting blood glucose, CRP, alkaline phosphatase, anti-nuclear auto-antibodies, anti-neutrophil cytoplasm auto-antibodies). Abdominal ultrasound revealed a solid intra-abdominal mass hypoechoic, heterogeneous, rounded, well limited, vascularized on Doppler, localized at the level of the left hypochondrium, of pancreatic origin.

Abdominal computed tomography showed a heterogeneous solid cystic tumoral mass in the

corporeal-caudal region, well-encapsulated, well limited, without infiltration, without peripheral lymph nodes with homogeneous contrast uptake, and without vascular invasion or remote secondary localization. (Figure 1).

Surgical treatment was performed by midline supraumbilical laparotomy; on exploration: there was no peritoneal carcinomatosis. After the opening of the posterior cavity of the omentums, we found a rounded and well-defined tumor sitting at the corporate-caudal level of the pancreas with no visible lymphadenopathy. A frozen section histological examination was performed, showing a well encapsulated tumor. A lumpectomy by pancreatic enucleation was performed (Figure 2).

The anatomopathological study of the surgical specimens showed a brownish piece, firm, well encapsulated, measuring 12x8x7 cm, of hetero-geneous brownish-white content with necrotic-hemorrhagic changes and a well-encapsulated lymph node of 1cm long axis without tumor invasion or vascular embolism. On histological examination, it was a solid pseudopapillary tumor of the pancreas with reactive lymph node hyperplasia.

The postoperative follow-up was simple after a postoperative hospital stay of seven days without adjuvant therapy without complications of pancreatic fistula. With a follow-up of 2 years, the patient is in good general condition with no clinical or CT scan recurrence.

III. DISCUSSION

The pseudopapillary tumor of the pancreas is a rare exocrine pancreatic tumor in the order of 2% and accounts for less than 5% of cystic tumors of the pancreas [4]. It was described by Frantz in 1959[5]. They are low-grade malignant tumors composed of poorly cohesive uniform epithelial cells forming solid, pseudopapillary structures. [4]. There are less than 1000 cases reported in the literature, mainly in the form of isolated instances. Similar to our patient, it is a predominantly female tumor with a sex ratio of 0.18. It occurs at a young age, with an average age of 29.3 years [6]. Its pathogenesis remains poorly

understood; its female predominance may be linked to hormonal factors [7]. Most of the series in the literature find a black or Asian ethnic origin, such as our patient [6.8].

The preferential localization of this tumor is corporeal-caudal in 64% of cases. However localizations at the level of the head of the pancreas or even extra-pancreatic can be found. [1,2]. In our case, the tumor was found in the body of the pancreas. It is a solid mass delimited by a capsule and associating areas of hemorrhage, necrosis, and calcifications. Symptoms are generally not specific, often incidental discovery of an abdominal mass, or abdominal pain with signs of digestive compression, depending on the size of the tumor [9] which explains the symptoms of our patient by compression. There are no specific biological signs of the pseudopapillary tumor of the pancreas. The immunohisto-chemistry examination, coupled with the histological examination, poses the diagnosis of certainty of the disease[10]. Immunohisto-chemistry is a very efficient examination but not routinely available in our country. Pancreatic pseudopapillary tumors are usually located in the tail of the pancreas. It is a large tumor containing solid and cystic components due to necrosis, hemorrhage, and cystic degeneration. The radiological aspect of the cancer shows a well-encapsulated, heterogeneous complex mass with solid and cystic components[1]. Abdominal ultrasound, most often finds a well-limited cystic mass with regular contours, poorly vascularized, with heterogeneous contents and no interior partitions, such as our case. Computed tomography is the most requested examination and better than ultrasound in terms of precision, which finds the same characteristics on ultrasound with partial enhancement in the periphery after injection of the contrast product without invasion of neighboring organs and possible intra-tumoral hemorrhage and calcification consistent with our case [1].

Despite the superiority of MRI over computed tomography and ultrasound, our patient could not benefit from magnetic resonance imaging because of the very high cost. In addition, the clinical symptoms associated with ultrasound and

computed tomography were sufficient to establish the indication for primary surgery.

We proceeded to surgery alone without preoperative biopsy, thanks to anamnestic, clinical, and radiological evidence. According to the literature, the reference treatment is complete resection by cephalic duodenal-pancreatectomy, if the tumor is located in the head or body and partial pancreatectomy with partial splenectomy in the event of a tumor located in the tail of the pancreas, especially in case of capsular rupture or invasion of neighboring organs [2], In our case, a spontaneous, an impromptu histological examination was done intraoperatively which showed a well-encapsulated tumor which motivated us to perform pancreatic enucleation.

The advantage of our choice allows decreasing the morbidity and mortality compared to the cephalic duodenal pancreatectomy in front of a well-encapsulated tumor without capsular rupture or lymph node invasion. The risk of tumor recurrence varies from 0 to 14%[11] ; with a follow-up of 2 years, no reproduction was reported in our case. According to the literature, the place of chemotherapy and radiotherapy is in the managing of unresectable tumors with lymph nodes or distant metastasis [12]. Even in metastasis, the prognosis for long-term survival is good[6]. In our patient, we did not perform chemotherapy.

IV.   CONCLUSION

The pseudopapillary tumor of the pancreas is a relatively rare, the symptomatology of which is not specific. The diagnosis of certainty is based on histology coupled with immunohistochemistry.

Imaging examinations make it possible to locate and help with tumor resection. A pancreatic enucleation can be practiced before a solid pseudo-papillary tumor of the pancreas, well encapsulated without lymph node invasion or capsular rupture on histological examination. With a low recurrence rate and a good survival prognosis.

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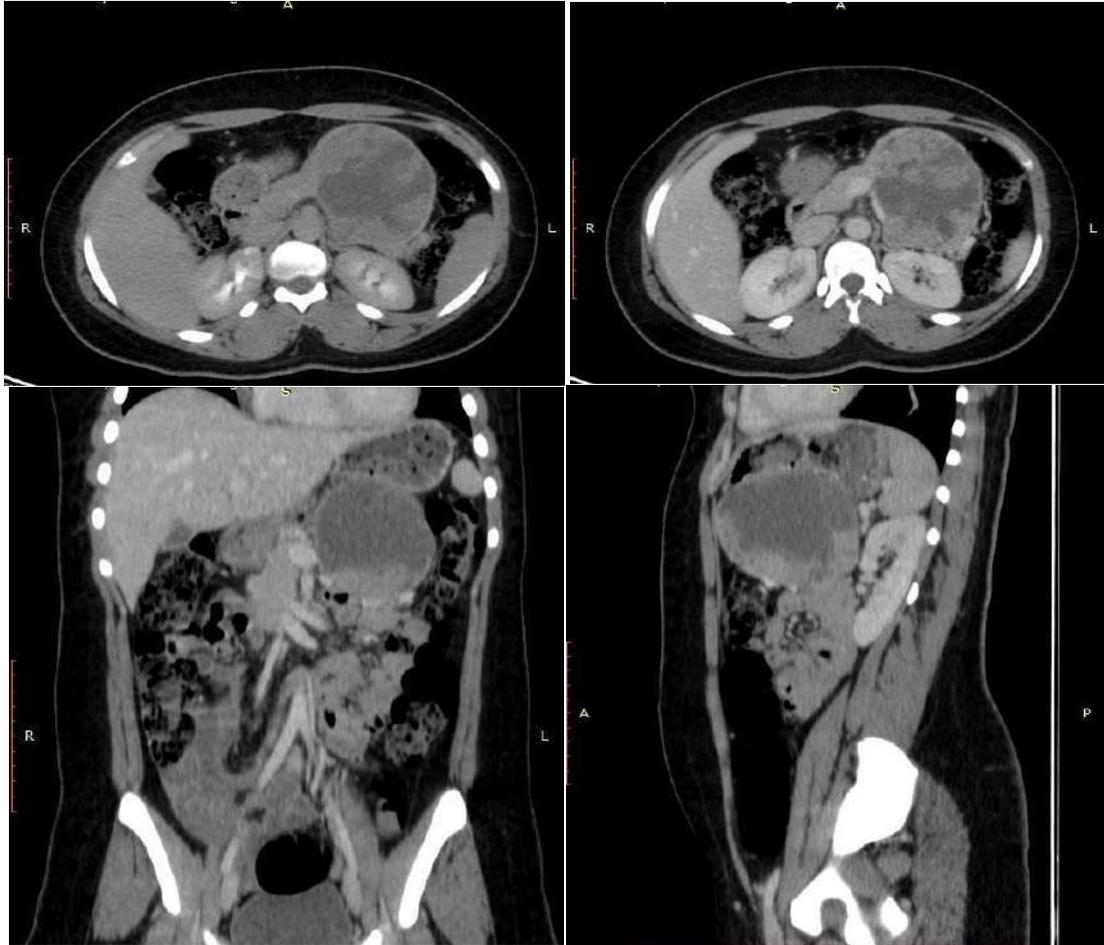
Figure 1: Abdominal CT Images of Our Patient in Transverse, Coronal, and Sagittal Sections Showing the Typical Characteristics of the Pseudopapillary Tumor of the Pancreas
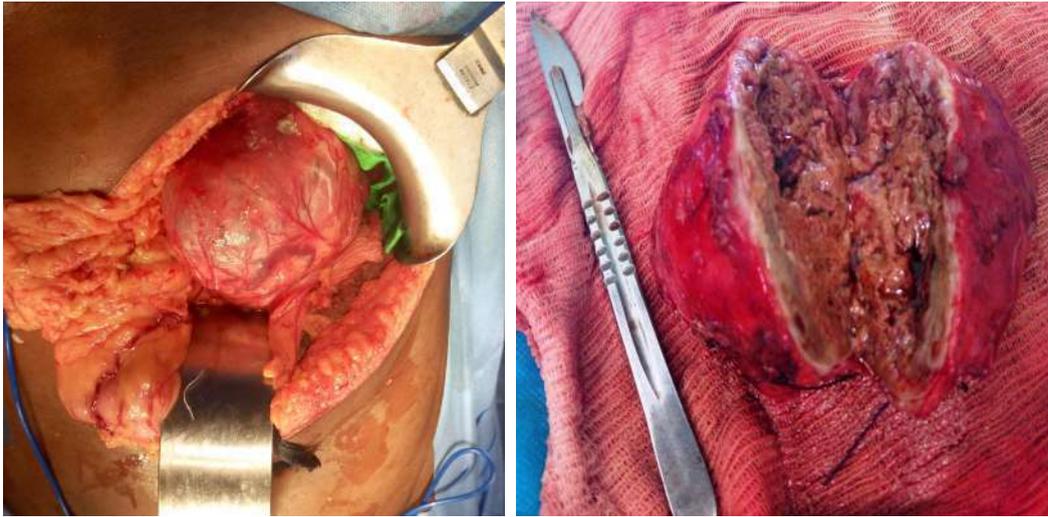
Figure 2: Intraoperative Image of Our Patient Showing Tumor's Location at the Level of the Tail of the Pancreas and the Intratumor Content

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Analyzing the Effectiveness of Digital Technology in Vaccine Supply Management in Kano State, Nigeria

Metiboba, L., Katuka, A., Thompson, A., Giwa, Z., Fagge R., Haidar, N, Akpan, D, Howeidy F. & Ngwokwe, I.

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ABSTRACT

Background: Poor vaccine stock management is a major challenge to targeted immunization coverage in Nigeria. Digital health tools are used to promote public health interventions. This study evaluated the impact of LoMIS Stock, a digital health tool, on vaccine stock management in Kano State. We deployed the quasi-experimental design using a mixed method to generate data for impact. We interviewed 109 stakeholders (66 in Kano; the state exposed to LoMIS; 43 in Bauchi; the comparison state). We measured LoMIS Stock usage rate, timeliness of reporting, facility stock-outs, and data-driven decision-making. The Analysis of Variance and T-tests were used to determine effect and compare difference of means. Using time series analysis (expert modeler), we forecasted the trend of stock-outs in Kano State if LoMIS Stock had not been introduced. All qualitative data was analyzed with Atlas Ti software.

Keywords: routine immunization; vaccine; LoMIS; stock-outs; vaccine visibility; health facility.

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Results: We found that 62% of participants reported using the tool for stock reports three years after its deployment. Twenty-four (24) hour response to stock-out alerts and Cold Chain Equipment breakdown improved by 67% and 49% respectively. Significantly, stock-out alerts reduced by 88% as compared to only 29% in Bauchi State within the same period. It was found that stock-out events would have increased if LoMIS Stock had not been introduced in Kano State. All partners interviewed affirmed the impulse of LoMIS on improved vaccine visibility that led to timely response.

Conclusions: LoMIS stock has significantly reduced stock-out experiences and improved vaccine visibility and accountability in health facilities. There are more opportunities for LoMIS Stock optimization.

Keywords: routine immunization; vaccine; LoMIS; stock-outs; vaccine visibility; health facility.

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I. INTRODUCTION

Full routine immunization for children below 24 months now costs between US$37 and US$101 across different settings in low- and middle-income countries as more and costlier vaccines are being introduced into national immunization programs [1]. The rising cost of vaccine and vaccine distribution, global supply shortages, and the introduction of new vaccines have provided the impetus to deploy a real-time management system to negate the uneven distribution of vaccines, improve efficiencies and allow better visibility of the vaccine supply chain [2,3].

A robust vaccine cold chain and logistics system including storage and transportation is the

cornerstone of all immunization programmes [4]. Rigorous supply planning based on accurate data should enable such a system to have the right vaccines in the right place, at the right time, in the right quantities, in the right condition, and at the right cost [3].

The 2021 Multiple Indicator Cluster Survey-National Immunization Coverage Survey (MICS-NICS) report showed that only about 44.2% of all children between 12-23 months old have received all basic vaccination doses in Nigeria; while only about 40% of those aged between 24-35 months had received all the recommended vaccines on the national immunization schedule in Nigeria in 2021 [5].

These indicators for measuring RI performance have shown slow progress in full immunization coverage in Nigeria despite huge investments and improvements in supply chain and distribution of vaccines in the last 5 years. However, the increasing incidence of stockouts and disrupted access to vaccines is of growing concern [3]. The majority of these stockouts are a result of internal issues such as inaccurate forecasts, stock management issues and restock delays [6].

Vaccine supply chain management systems have been prominent features of the Expanded Programme on Immunization (EPI) plans from the onset [7]. System requirements have expanded dramatically over the past several years with the introduction of new vaccines and the frequent mass campaigns to control, eliminate, or eradicate specific diseases, such as polio, measles, rubella, tetanus. While such initiatives tend to be well-funded, the strain they place on the supply chain system are substantial and often not acknowledged, particularly at state levels [7]. The most visible impact of new vaccine introduction is an increase in the volume of products that need to be stored, transported, and tracked, as well as the need for more storage capacity due to the increased use of single-dose vials [8].

These further exacerbates existing and new challenges in vaccine supply chain management like poor cold chain equipment inventory and status; poor vaccine stock, distribution and utilization data collection and management; lack of skilled and properly trained workers in vaccine management operations; poor vaccine storage facility; and unreliable micro-plan data which leads to wastage, stock-outs and overstock, and inequitable distribution of products [9,10,11]. It is important to note these challenges and many other vaccine supply chain management problems are related to inefficient database management systems and innovative digital tools [9,12].

In 2016, the Ministerial Conference on Immunization in Africa laid the groundwork for the landmark Addis Declaration on Immunization (ADI), including 10 commitments to achieve universal and equitable access to immunization in Africa. The ADI was endorsed by Heads of State from across Africa at the 28th African Union Summit in early 2017, signaling political support for immunization on the continent at the highest possible level [13]. Real-time data and digital tools were identified as a powerful instrument to advance these efforts. Digital platforms make it easy to assess progress and to revisit decisions along the way, instead of waiting for quarterly reports or midline assessments. Digital tools also democratize learning and decision-making, so that stakeholders at all levels of the health system can make meaningful use of data.

In response to these assertions, eHealth Africa, a non-governmental organization (NGO) was funded by the Bill and Melinda Gates Foundation (BMGF) and the Kano State Primary Health Care Development Agencies (KSPHCDA) to concep-tualize, design and roll out an electronic logistic management information system, LoMIS Suite to strengthen accountability and data-driven management in vaccine supply chain manage-ment in 2014. The Suite consists of an offline-capable mobile application "LoMIS Stock" and a web application and "LoMIS Deliver." LoMIS Stock was designed to help health care workers (HCWs) bypass the traditional paper-based reporting system and submit reports instantly using an app on their mobile device. The app was also built to enable supervisors to get near real-time visibility of stock inventory, consumption rate (vaccine wastage, stock out, utilization), cold chain status and cascade

deliveries from all locations where vaccines are stored. LoMIS Stock answers three critical questions "Where are my Vaccines? ""Are they sufficient?" and "Are they potent?" LoMIS Deliver on the other hand aggregate these reports on stock levels, equipment status, and vaccine utilizations into a single web dashboard for real-time data visualization of field operations.

Both applications are based on the structure and workflows of the KSPHCMB system.

1.1 Evaluation Questions

This study was conducted to answer the following research questions:

1. Is the LoMIS stock tool being used by the proposed users to report routine immunization vaccine supplies?
2. What is the effect of its use on the duration in reporting stock out and the turnaround time?
3. What is the impact of the tool on facility stock out experiences?
4. How has the tool supported the routine immunization stakeholders to plan for vaccine distribution?

1.2 Evaluation Objectives

In line with the research questions, we were guided by the objective of understanding the impact of using digital data management tools in vaccine supply chain management against the traditional paper-based systems in Kano state. Specifically,

1. To determine the use of LoMIS and the experiences of facility stock out prior and after the use of LoMIS stock tool in Kano state Nigeria
2. To understand effect of LoMIS Stock on vaccine supply planning and management in Kano state, Nigeria

1.3 Research Area

Kano state has an estimated population of approximately 14,994,830 according to the National Population Commission's 2019 projection. A district health information system 2 (DHIS2) tool with a customized routine immunization (RI) module and indicator

dashboard was introduced in Kano State, Nigeria, in November 2014 to improve data management and analysis of RI services. A district health information system 2 (DHIS2) tool with a customized routine immunization (RI) module and indicator dashboard was introduced in Kano State, Nigeria, in November 2014 to improve data management and analysis of RI services [14]. DHIS2 has recorded the following success on RI coverage based on integrated technical solutions and interventions. The average routine immunization coverage rate (Penta 3) in Kano state from 2014 till 2021 is 83.9% as shown in Figure 2. The selected study Local Government Areas (LGAs) within Kano and Bauchi states are indicated in Figure 1.

Figure 1: Map Showing Study Locations in Kano and Bauchi States, Nigeria

Source: DHIS2

Figure 2: Trend of Penta 3 Coverage (%) in Kano State, Nigeria

Bauchi State, according to the National Population Commission of Nigeria, has an estimated population of approximately 6.3 million people. In 2022, RI coverage in Bauchi State reached 83% as indicated in Figure 3. The Bauchi State Government, through its Task Force on Primary Health Care continues to make a strong commitment to ensuring the availability of adequate stock of vaccines, essential medicines, and consumables in health care facilities, through an improved supply chain system and Drug Revolving Fund.

Figure 3: Trend of Penta 3 Coverage (%) in Bauchi State, Nigeria

1.4 Research Limitations

The main limitation encountered in this paper is the quality of data and data availability in the DHIS2 data. Especially in Kano state, we were unable to conduct robustness checks on stock out by vaccines due to the unavailability of data.

II. STUDY DESIGN AND METHODS

2.1 Study Design

We employed the quasi-experimental design using a mix of quantitative and qualitative research methods to determine what would have been the outcomes in Kano state if the digital tool (intervention) had not been utilized. In this study, we identified Bauchi State vaccine supply chain management system as the comparison group based on validated evidence that Bauchi state was utilizing the paper-based reporting tools for vaccine stock inventory as of the period of this study.

2.2 Sampling techniques

Our study respondents were selected by using a three multi-stage sampling technique to select and recruit sixty (60) and forty (40) Ward Technical Officers/Routine Immunization Officers (10) for the intervention (Kano state) and the comparison (Bauchi state). We stratified all the state LGAs under the three senatorial zones in both Kano and Bauchi States and used a purposive sampling approach to select 6 LGAs under the 6 Administrative Zones of Routine Immunization in the Kano State, and 4 LGAs under the 2 Administrative Zones of Routine Immunization in Bauchi State based on their geographical proximity to each other. Ten (10) Ward Technical Officers (WTOs/RIOs)

representing 10 wards from the selected LGAs in both states were randomly selected for the study.

The WTOs from Kano State were users of the Mobile Application (The Health Facility In-Charge) and Dashboard (State and Development Partners in Kano State) while the WTOs from Bauchi State (comparison participants) were Routine Immunization Officers/HFiC and development partners.

2.3 Data Collection and Analysis Methodology

Primary data for this study were collected using the evaluation tools (structured questionnaires and Key in-depth interviews) while secondary data was collected from records on the LoMIS Dashboard and District Health Information System Software (DHIS2). LoMIS dashboard is a platform that enables near-real-time visibility, storage, and retrieval of vaccine stock inventory while DHIS2 enables the collection, storage, retrieval and management of case-based data records. The primary data sources provided information on duration of reporting vaccines, duration of response to reports, and the benefits of LoMIS. The secondary data sources also provided information on the duration of vaccine reports and duration of response to those reports. The secondary data sources provided more information including the usability of LoMIS, availability of stock or stock-out.

All quantitative data was entered, analyzed using Statistical Package for Social Science (SPSS,). Analysis of Variance (ANOVA) was employed to determine the effect of the LoMIS tool on stock-out data in Kano. Paired and independent t-tests were used to determine the significance of the mean difference between stock-out data between pre/post-LoMIS and to compare

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stock-out reports in Kano and Bauchi respectively. To further understand the impact of LoMIS on stock-out occurrences in facilities, time series analysis (Expert Model) was used to predict 12 months (August 2014 - July 2015) trend of stock-out if LoMIS was not introduced as a reporting tool in Kano State. Qualitative data analyzed with the use of Atlas-ti, thematic results in both States were analyzed and compared.

immunization areas across Kano (73%) and Bauchi (90%) states (Figure 4). Study participants in Kano (40%) and Bauchi (60%) have worked as WTO/RIO for more than 3 years. All State and development partners interviewed have had relevant work experience as key decision makers whilst planning and managing RI vaccine supplies in Kano and Bauchi States.

III. RESULT AND DISCUSSION

3.1 Respondent's Demographics

In this study, it was found that males are the predominant staff working within the routine
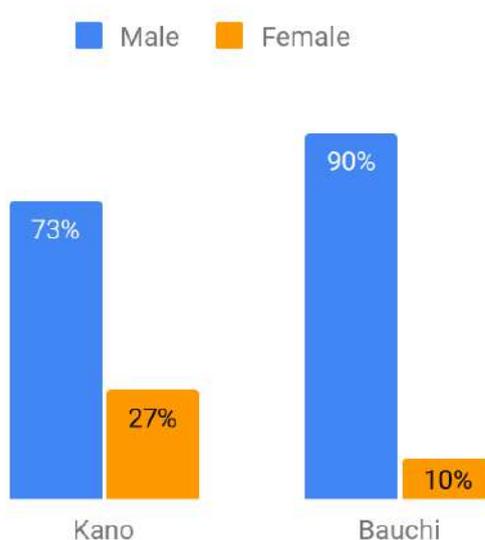
Source: Study Survey data

Figure 4: Sex of Participants Across the Study Locations

3.2 Analysis of findings by Research Questions

3.2.1 Research Question 1: The Utilization of LoMIS Mobile Application Tool in Reporting Vaccine Stock Inventory in Kano State (Usability Rate)

Findings from the desk reviews revealed that 484 facility personnel had been trained on how to use LoMIS Stock app for vaccine stock inventory. Analytics from LoMIS Dashboard showed 82% usage rate, that is, 397 of 484 Ward Technical Officers had used LoMIS application to report at least one stock inventory. Among all (60) users of

the tool interviewed 60% are current users of LoMIS Stock as of the period of study.

Non-current users (40%) of LoMIS Stock have had experience of its use but issues related to network and faulty/missing phones stopped them from using LoMIS in reporting vaccine stock inventories. The LoMIS web dashboard further revealed increased use of the tool over time. As of December 2017, the usability rate had improved from 105 (22%) (January 2015) to 304 (63%) resulting in 190% increase in usage rate (Figure 5). As expected, the survey findings affirmed that Bauchi state was only using the paper-based reporting tool as of the period of study.

190% Increase in usage

Peak of use
(Period of
Scale-up)

Users of LoMIS at
End-line
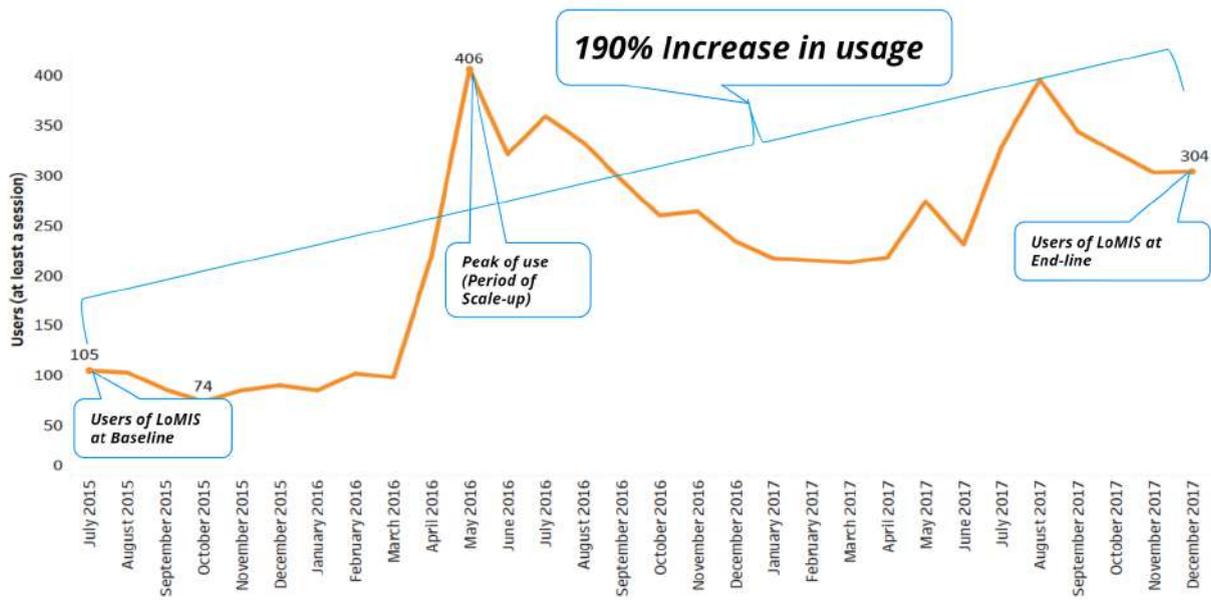
Users of LoMIS
at Baseline

Figure 5: Users of LoMIS Application Overtime

3.2.2 Research Question 2: Duration of reporting RI vaccine stock inventories and turnaround time

The findings related to the amount of time it takes to report RI vaccine inventories via LoMIS Stock in Kano state and the paper-based tools in Bauchi state were compared. In Kano state, it was found that 67% of respondents reported that it takes Pop more than 10 minutes to complete the process of reporting vaccine stock inventories via the paper-based tools while 100% of the respondents reported an average of 5 minutes to complete a report via LoMIS Stock. This is consistent with the findings from the comparison group (Bauchi State) where 63% of them reported spending more than ten minutes whilst reporting through paper-based tools.

Findings from the tool dashboard validates the duration of reporting via LoMIS. Users of LoMIS application tool used an average duration of less than 5 minutes on any stock inventory form as illustrated in Figure 6.
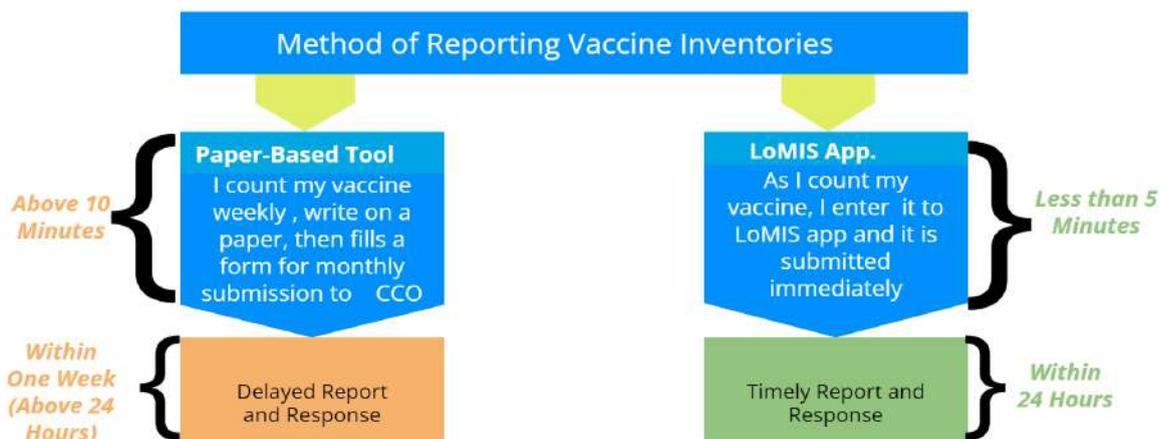
Figure 6: Impact of Lomis Stock Tool on Ri Vaccine Inventory Reports and Turnaround Time

Qualitative responses elicited through the interviews conducted further validates improvement in timely report of vaccine stock.

"With LoMIS, I can report in just two to five minutes and can get a response in a day or two. LoMIS is really supporting my work very well because it has many purposes."

State Partner, Kano

Respondents in Bauchi State on the other hand gave unreserved complaints on the use of paper-based tools to report vaccine stock. Majority of the challenges identified is time wastage which LoMIS Stock has been able to address in Kano State

"Paper-based reporting tools are tedious and time-consuming ......"

State Partner, Bauchi

In Kano state, it was found that out of the 39 respondents that provided answer to the question of average response time to stock out reports, 34 **(57%)** reported that all stock-out reports done through the LoMIS tool got response under 24 hours as compared with **20%** that got response under 24 hours prior the use of LoMIS stock.

Twenty-two **(59%) of 37 responses revealed that** Cold Chain Equipment breakdown through LoMIS got a response within 24 hours as compared to **10%** who got a response in 24 hours before the use of LoMIS (Figure 7).
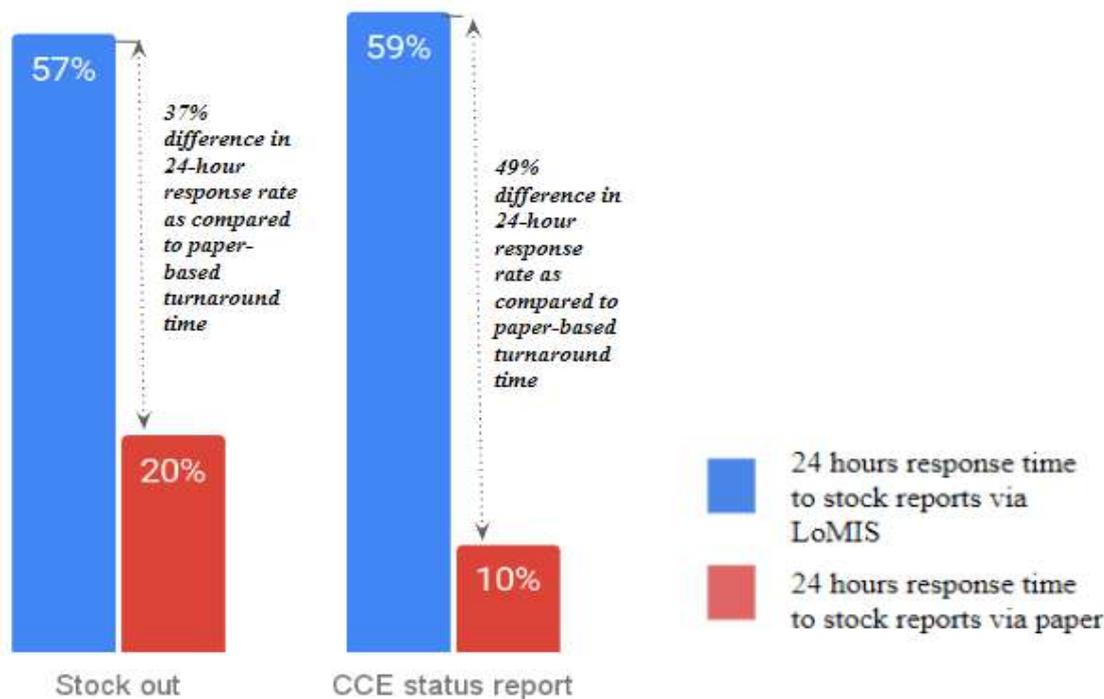
Source: Study survey data

Figure 7: Comparing the Reported Improvement in 24-Hour Response to Stock Out and Cce Reports via Lomis and Paper-Based Tool in Kano State

3.2.3 Research Question 3: The Impact of LoMIS Stock on experiences of RI vaccine stock-out at facilities

Another major finding from this assessment study is reduction in stock-out experiences in health facilities. It was found that 60% of facilities had at least reported an event of stock-out from January 2014 through December 2017. The trend analysis further showed that the percentage of facilities experiencing stock-out reduced with time in Kano state. Within 3 years of using the LoMIS tool, the number of facilities experiencing stock out reduced by 92% in Kano (LoMIS) as compared to only 42% reduction in Bauchi (paper-reporting tool) within the same period (Figure 8).
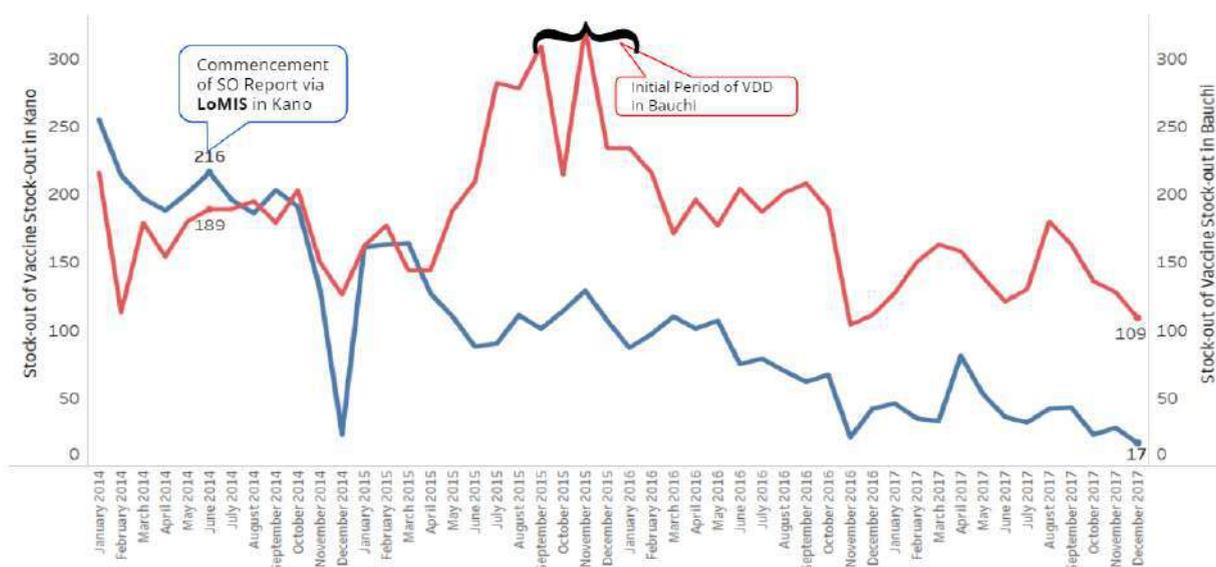
Figure 8: Trend of Stock Out Experiences in Kano and Bauchi State Prior and After the Use of LoMIS

At baseline, stock-out experiences in health facilities in Kano and Bauchi States were of similar figures. However, stock-out occurrences in Kano experienced drastic reduction over time as compared to Bauchi State (Figure 8). In addition, the differences in stock out outcomes in Kano and Bauchi states were confirmed as the Analysis of Variance (ANOVA) showed that the effect of the reporting tool on stock-out was significant (F $(1,70,)$ = 215.506, p = 0.000). The comparison analysis using a paired-sample t-test showed that the mean difference in facility stock-out between a 3-year period prior and after LoMIS was found to be statistically significant (p=0.000) (Table 1).

This implies that LoMIS significantly contributed to reduced experiences of vaccine stock-out in health facilities. The independent sample T-test also revealed a huge significant difference between the means of facility stock-out in Kano (use of LoMIS) and Bauchi (Paper-tool) with a large effect size. Again, this result further validates the contribution of LoMIS to reduced vaccine stock-out in Kano (Table 2).

Table 1: Difference in Facility Stock-Out Prior/Post LoMIS Stock in Kano State

Period	Mean	SD	SE	P Value	
Pre-LoMIS (January 2012 - June 2014)	246.58	61.68	10.28	0.000**	
Post-LoMIS (July 2014 - December 2017)	79.22	41.57	6.9		
	Mean Difference				
Paired Differences	Mean	SD	CI	T	P Value
Pre-post stock-out	167.36	48.40	150.98 -183.73	20.74	0.000*

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Table 2: Difference in Facility Stock-Out in Kano and Bauchi States: Stock-Out: LoMIS (Kano) vs Post-LoMIS (Bauchi)

	Mean	SD	SE	t	MD	Cl	P Value
Kano (LoMIS) Bauchi (Paper-based Tool)	90.02	52.77	8.14	- 8.01	- 91.09	Lower: -113.71 Upper: - 68.47	0.000*

3.2.4 Research Question 4: The Impact of LoMIS Stock on Data-Driven RI Vaccine Supply Planning and Management

In this study, it was found that LoMIS Stock has enabled near-real time RI vaccine reports, and this has led to improved visibility to the status of RI vaccines across health facilities in Kano state.

Enhanced vaccine visibility has enabled most of the decision makers to respond to stock-outs, CCE breakdown and over-stock of vaccines immediately. The planning RI vaccine supply has been influenced by the distribution data of RI vaccine status across the facilities.

"With LoMIS Dashboard, the status of the vaccine has been visible, that is visibility of stock availability. This helps me to take decisions in time."

"I use LoMIS Dashboard weekly to ensure there is no Stock Out in any facility. I also identify any CCE breakdown for replacement or repair. Recently, I saw Stock-out of BCG in a facility on the Dashboard and called the facility immediately."

State Partner, Kano

LoMIS is really an engine room, it's a bank for information on vaccine management. At a go, it is easy to see the status of CCE and make decisions at a go too. Non-functional CCE receives speedy repair.

Development Partner, Kano

"LoMIS is real time, for me, I see the status of vaccines immediately and I also have the contact of service providers and I just call. It helps my daily plan. For me, I go on LoMIS every day.

Development Partner, Kano

3.2.5 Research Question 5: Predicted occurrence of facility stock-out with Paper-reporting tools in Kano

To better understand and appreciate the contribution of LoMIS to reduced facility stock out in Kano; time series analysis (Expert Model) was used to forecast a 12-month (August 2014-July 2015) trend of occurrences of stock-out if LoMIS Stock was not introduced as a reporting tool in Kano State. The analysis showed that the trend of high stock-out prior July 2014 would have continued to be the situation if LoMIS Stock was not utilized. It was found that the trend of forecast data in Kano quite synchronizes with the observed stock-out data in Bauchi State (Figure 9). This further validates the effect of LoMIS on reduced stock-out occurrences in Kano state.

Figure 9: Time Series Analysis: 12 Months Forecast of Stock-Out if LoMIS was Not Introduced

IV. DISCUSSION

We conducted a comprehensive assessment of the impact of LoMIS Stock reporting tool on vaccine stock management in Kano state. The results showed that LoMIS Stock has contributed to effective vaccine management in terms of real-time reports, vaccine visibility and accountability. These have led to timeliness of report, increased response rate, reduction in facilities experiencing stock-out and eventually availability of adequate stock at the last-mile facilities. The findings from this study further corroborates the results of several studies on the impact on the use of digital tools as an effective approach to public health interventions globally [15,16,17,18].

In Nigeria, one of the challenges of vaccine stock management occurs because of poor vaccine stock visibility at health facilities [19]. Our study has shown that this challenge can be significantly addressed with a digital tool as we found that the use of LoMIS Stock for reporting vaccine stock inventory enhanced access to vaccine stock distribution across the focal facilities. The usability rate (82%) of LoMIS Stock shows that the use of digital tools is a prioritized solution to the challenges of public health interventions in low- and middle-income countries like Nigeria.

This corroborates the findings of a digital health study where it was found that digital technology is a feasible and acceptable approach for public health interventions [20]. Specifically for immunization interventions, a recent study reported high acceptability rating amongst vaccinators and district managers for an iterative mobile-app that was developed to track immunization encounters in Pakistan which shares similar public health demographics with Nigeria [21]. In another study in Malawi, end-users assessed the usability of two digital tools for community case management of under-five children—highlighting that although both tools are useful in gathering important intervention data, their usability differs by a wide margin and this determined the overall success of the tool in supporting health interventions in the study setting [22]. This implies that the ease-of-use that was recorded with the end-users of the LOMIS Stock App contributed significantly to the success of the tool in managing vaccine supply chain management in Nigeria.

We found that the amount of time needed to complete a report of RI vaccine inventory significantly reduced using a digital health tool.

The paper-based responses in Bauchi State validates improvement in duration of response time using LoMIS Stock in Kano State as the

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responses were consistent with pre-LoMIS findings in Kano State. In another study, the results also posits that the use of digital technology for reporting routine immunization data is feasible and can provide real-time updates to RI performance indicators such as vaccine availability [23].

In addition, this study sought to assess the impact of the digital tool on facilities experiencing stock-out; and we found that the stock-out experiences reduced over time in Kano state.

Within 3 years of using the LoMIS tool, the facilities experiencing stock out reduced by 92% in Kano (LoMIS) as compared to only 42% reduction in Bauchi (paper-reporting tool) within the same period. The implication of this result is that there was sufficient stock of death-preventing vaccines at health facilities in the study location.

This finding strengthens the discussions around the value of developing and implementing digital health tools in public health interventions [24].

Furthermore, the impact of the tool, LoMIS Stock on vaccine planning and management was significant as our results showed that the LoMIS dashboard tool enhanced the vaccine operations visibility—providing near real-time data that enabled key decision makers to respond to stock-outs, CCE breakdown, and vaccine over-stock in record time, and ensure that immunization efforts meet expectations. Improved planning and management organization is another notable impact of the LOMIS dashboard on decision makers in the study location as we recorded in this study. This further contributes to existing evidence that data dashboards in public health tools provide reliable information to inform and support policy makers and project managers in iterating public health interventions [25]. Several sources show that a wide range of COVID-19 response interventions utilized many dashboards to collect data on time series, geographic maps, case incidents, contact tracing, community surveillance and clinical trials to refine intervention approach, outputs and outcomes [26,27,28,29]. A similar result was obtained by another researcher where a proactive infection prevention and control (IPC) monitoring

tool was pioneered to provide reliable data for real-time response to emerging risks to COVID-19 infection amongst healthcare workers in Guangdong Second Provincial General Hospital in China. The study showed that the worrisome rate of healthcare workers infection prior to the deployment of the tool was reduced; and future plans to integrate artificial algorithms to the tool for improved outcomes are already being muted [30].

V. CONCLUSION

The implication of this result is that there was sufficient stock of death-preventing vaccines at health facilities in the study location. This finding strengthens the discussions around the value of developing and implementing digital health tools in public health interventions [24].

Furthermore, the impact of the tool, LoMIS Stock on vaccine planning and management was significant as our results showed that the LoMIS dashboard tool enhanced the vaccine operations.

participants provided written consent before participating in the study.

Informed Consent

All participants provided written informed consent before participating in the study.

Competing interests

The authors declare that they have no conflicts of interest.

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A Patient with Symptomatic Polyostotic Melorheostosis Successfully Treated with Intravenous Zoledronate Injection- A Case Report

Chandrarathne D.K.S.J, Kalaventhan P, Mendis D.C.D, Ganegama R & Deepal C

ABSTRACT

Introduction: Melorheostosis is a rare congenital bone disorder present with insidious onset of bone pain. Diagnosing this rare condition and managing it is difficult. Knowledge of this rare entity is important for the physician who is treating patients with musculoskeletal pain.

Case Report: A 25-year-old female with right leg pain for a two-year duration. She has been seen by a lot of physicians and could not have been managed properly. Her radiographs were showing hyperostotic left ulna and right tibia. Sinister pathologies were excluded using MRI and biopsy. Her symptoms settled with intravenous Zoledronate. Pain recurred after two years and she responded well after repeated Zoledronate injection.

Keywords: polyostotic melorheostotis, zoledronic acid, osteoclasts.

Classification: NLM Code: WE 300-400

Language: English

A Patient with Symptomatic Polyostotic Melorheostosis Successfully Treated with Intravenous Zoledronate Injection-A Case Report

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ABSTRACT

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Conclusion: Though there are no key clinical features, diagnostic tests, or cause of this clinical condition, symptomatic management is adequate to manage patients with this clinical condition. Intravenous Zoledronic acid is an option for patients who have severe and resistant symptoms.

Keywords: polyostotic melorheostotis, zoledronic acid, osteoclasts.

I.   INTRODUCTION

Polyostotic melorheostosis is a rare congenital non-hereditary benign sclerosing mesenchymal dysplasia involving multiple bones(1−4). Melorheostosis is presented in the second decade of life. The male and female ratio is the same. The classical description of appearance in the radiographs is "flowing candle wax"(1). The axial skeleton is rarely involved. The treatment is mainly non-operative. Surgery is reserved for the lesions complicated with fractures.

We present a case report on a patient with symptomatic polyostotic melorheostosis successfully treated with intravenous Zoledronate injection.

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II.   CASE REPORT

A 25-year-old female presented to the orthopaedic unit with pain over her right leg left forearm and back for two years duration. She has been seen by a lot of physicians for the same ailment and they could not help her. The pain gradually worsened over time and made her visit us. On examination, the right leg and the left forearm were swollen diffusely. There is no history of back pain.

Radiographs show hyperostosis of the right tibia and the left ulna (Figure 1). Technetium 99 bone scan revealed hyperactivity seen on the right tibia, left ulna, left fibula, left femur and the spine (Figure 2). The bone profile including serum calcium, phosphate and alkaline phosphate was normal. Bone biopsy revealed normal bony architecture. She was given an intravenous Zoledronic acid injection and became asymptomatic. She was followed up at the

Orthopaedic clinic for two years. Again, she developed pain over the same region and she was treated again with the same medication. Now she is completely pain-free and her activity of daily living has improved dramatically.

Figure 1: Shows radiographs of symptomatic anatomical regions show polyostotic sclerotic bony lesions involving the left proximal ulna (Figure 1A), right tibia (Figure 1B), left fibula (Figure 1C) and left proximal ulna (Figure 1D). All lesions are identical and have scalloping edges compatible with the classical description of the disorder.

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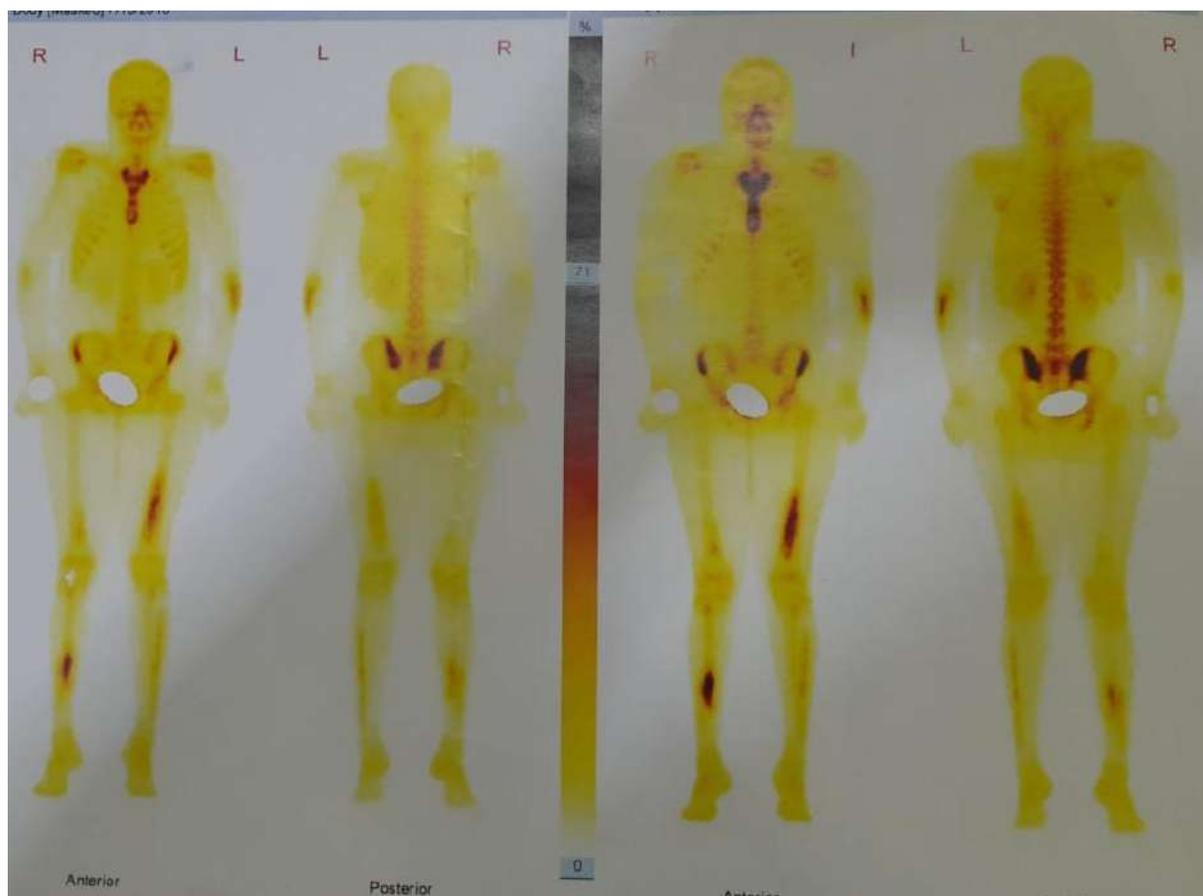
Figure 2: Shows the whole body Technetium bone scan of the same patient which revealed hyperactivity seen in the right tibia, left ulna, left femur and left fibula. In addition, the spine and pelvis also show hyperactivity.

III.   DISCUSSION

Melorheostosis is a rare disorder in which sclerosing dysplasia with derangement in endochondral and intramembranous ossification of bones. The summary of demographical details is in Table 1.

Demographic Details	
1. Incidence	0.9/Million
2. Male: Female	1:1
3. Age of presentation	2-64 years
4. Majority of presentations at the age of	Around 20 years

Figure 3: Summary of demographic details of patients with melorheostosis (1, 2, 4, 5)

These lesions can be on one bone (Monostotic), many bones (Polyostotic), involving one limb (Monomelic) or generalized. Axial skeleton involvement is rare. According to the anatomical involvement, severity and the deformity caused by the lesions symptoms and signs will be varied.

Commonest symptoms are painful limb swelling, restricted range of motion and contractures of joints (usually asymmetric). Axial skeleton involvement may present with back, and neck pain,radicularpain,scoliosis,stiffness,giddiness,symptomsofvertebrobasilarinsufficiencyandevidenceofcord compression(1).

Melorheostosis is not a fatal condition. But it impacts significantly the activity of daily living of patients with this ailment. The management of melorheostosis varies from simple analgesics to surgery. The management depends on the

A Patient with Symptomatic Polyostotic Melorheostosis Successfully Treated with Intravenous Zoledronate Injection- A Case Report

anatomical site, the extent of lesions, the severity of symptoms and the degree of deformity. The primary goal of management is to relieve symptoms and achieve mobility. Pain relief, nerve blocks, braces, and physiotherapy play a vital role. Patients who are not responded to these options will undergo nerve blocks. Surgery deserves for patients with lesions complicated with fractures.

There are few case reports on the usage of intravenouszoledronatefor melorheostosis(6–8). They reported successful outcomes following treatment after the injection. On our patient single dose of intravenous zoledronic acid (5mg over 30 minutes) has provided remission for two years and it worked for relapse as well after two years. Intravenous zoledronate is an effective treatment for symptomatic polyostotic melorheostosis. Zoledronate is a bisphosphonate which inhibits osteoclasts and reduces bone pain, prevents pathological fracture and reduces blood supply(6–8). Bone resorption by osteoclasts, stimulation of pain receptors and increased intraosseous pressure are major reasons for bone pain among patients with melorheostosis (6–8). Thus, zoledronate is a viable option for the ents with melorheostosis causing bone pain. Anyway, careful selection of patients and preparation is necessary before the zoledronate infusion to avoid complications (Avascular necrosis of the jaw, fever, allergic reactions etc).

IV. CONCLUSION

Symptomatic polyostotic melorheostosis may be resistant to symptomatic treatment. Intravenous zoledronate is a viable option for such patients.

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Breast Cancer in Middle-Aged Women: A Literature Review

Rafaela Lima Monteiro

ABSTRACT

Mammary neoplasia consists of the disorderly proliferation of defective cells in the mammary ducts, resulting from several factors that drive their development in the tissue. The objectives of this work are: to verify the incidence of breast cancer in middle-aged women, and to identify possible risk factors for the onset of breast cancer in middle-aged women. An integrative literature review was carried out with searches in the Lilacs, Pubmed and Medline databases. The DeCS were used: "Breast Neoplasms", "Middle-Aged Person", "Risk Factors" and "Post-Menopause", in Portuguese and English, crossing with the Boolean operators AND and OR. Inclusion criteria were: complete articles; published in Portuguese, English and Spanish, between the years 2018 and 2022, available in full and free of charge.

Keywords: breast neoplasm; middle-age; post- menopause; risk factors.

Classification: NLM Code: WP 870

Language: English

Breast Cancer in Middle-Aged Women: A Literature Review

Câncer De Mama Em Mulheres De Meia Idade: Uma Revisão Da Literatura

Rafaela Lima Monteiro

RESUMO

A neoplasia mamária consiste na proliferação desordenada de células defeituosas nos ductos mamários, resultando de diversos fatores que impulsionam o seu desenvolvimento no tecidual. Este trabalho possui como objetivos: verificar a incidência de câncer de mama em mulheres de meia idade, e identificar os possíveis fatores de risco para o desencadeamento do câncer mamário nas mulheres de meia idade.

Realizou-se uma revisão integrativa da literatura com buscas nas bases de dados Lilacs, Pubmed e Medline. Foram utilizados os DeCS: "Neoplasias de Mama", "Pessoa de Meia-Idade", "Fatores de Risco" e "Pós-Menopausa", nos idiomas português e inglês, cruzando com os operadores booleanos AND e OR. Os critérios de inclusão foram: artigos completos; publicados em português, inglês e espanhol, entre os anos de 2018 e 2022, disponíveis na íntegra e gratuitamente. Já os critérios de exclusão foram: a não pertinência ao tema. Foram encontrados 122 artigos, e selecionados 08 para compor este estudo. Identificou-se que os principais fatores de risco para o desenvolvimento de câncer mamário estão relacionados a mulheres em período de pós-menopausa, ou seja, mulheres que estão na meia idade, são a obesidade e a produção elevada de estrogênio, etilismo, o histórico familiar e o padrão alimentar não saudável. Pode-se inferir que as mulheres em período pós-menopausa atrelados aos fatores de risco de desenvolvimento de câncer de mama necessitam de uma assistência pautada na prevenção de saúde, sendo por tanto assistida pela equipe de enfermagem, que deverá corroborar com a divulgação e incentivo da mamografia e autoexame das mamas para detecção precoce do câncer.

Palavras-Chaves: neoplasia mamária; meia idade; pós-menopausa; fatores de risco.

ABSTRACT

Mammary neoplasia consists of the disorderly proliferation of defective cells in the mammary ducts, resulting from several factors that drive their development in the tissue. The objectives of this work are: to verify the incidence of breast cancer in middle-aged women, and to identify possible risk factors for the onset of breast cancer in middle-aged women. An integrative literature review was carried out with searches in the Lilacs, Pubmed and Medline databases. The DeCS were used: "Breast Neoplasms", "Middle-Aged Person", "Risk Factors" and "Post-Menopause", in Portuguese and English, crossing with the Boolean operators AND and OR. Inclusion criteria were: complete articles; published in Portuguese, English and Spanish, between the years 2018 and 2022, available in full and free of charge. The exclusion criteria were: non-pertinence to the theme. 122 articles were found, and 08 were selected to compose this study. It was identified that the main risk factors for the development of breast cancer are related to postmenopausal women, that is, women who are in middle age, are obesity and high estrogen production, alcoholism, history family and unhealthy eating patterns. It can be inferred that postmenopausal women linked to risk factors for the development of breast cancer need assistance based on health prevention, being therefore assisted by the nursing team, which should corroborate with the dissemination and

encouragement mammography and breast self-examination for early detection of cancer.

I. INTRODUÇÃO

A neoplasia mamária maligna tem se tornado crescente ao longo da história da saúde da mulher, sendo a segunda maior causa de óbito dessa população no mundo. Possui alta incidência entre as mulheres e foi a principal causa de morte no Brasil no ano de 2017, com 16.724 óbitos (INCA, 2020). É importante que a equipe de saúde tenha um olhar pautado nas mulheres mais suscetíveis ao desencadeamento da doença, por isso vale ressaltar a importância do exame preventivo e mamografia para detecção precoce e bom prognóstico (LEITE; RUHNKE; VALELO, 2021).

Segundo o Instituto Nacional do Câncer (INCA) (2021), no Brasil a estimativa de câncer de mama para os anos do triênio 2020-2022 é de 66.280 casos novos, com a incidência de 61,61 casos novos a cada 100 mil mulheres. Sendo um crescente problema de saúde pública, principalmente entre as mulheres em período menopáusico e pós-menopáusico, que mesmo com ações de combate ao câncer de mama, permanece sendo um agravo alarmante no sistema de saúde do país (PEREIRA *et al.*, 2021).

O câncer de mama ou neoplasia mamária maligna resulta da falha das células do tecido mamário que começam a se reproduzir desordenadamente, podendo espalhar-se para outros tecidos e órgãos.

Diversos fatores são os responsáveis por contribuir para o seu aparecimento. O fator idade é um importante elemento nesse processo cancerígeno (MATOS; RABELO; PEIXOTO, 2021; INCA, 2021).

Nesse contexto, o período menopáusico é um período natural entre o sexo feminino que está caracterizado como a transição de um período menstrual para o não menstrual, marcando a cessação do período reprodutivo. Para algumas mulheres esse período pode ocorrer de forma precoce ou tardia (SANTORIO *et al*, 2021).

De acordo com a Organização Mundial da Saúde (OMS, 2021), essas mulheres em período menopáusico e pós-menopáusico, correspondente a 45-59 anos de idade, se encontram em processo de transição, estando mais suscetíveis ao aparecimento da neoplasia mamária devido a fatores internos em conseguinte as mudanças ocorrendo no seu corpo e fatores externos que podem ser modificáveis.

Tais fatores correspondem ao comportamento e ambiente, ao etilismo, tabagismo, sedentarismo, obesidade, hereditariedade, números de partos, terapia hormonal, menarca precoce. Estão entrelaçados para o desenvolvimento do câncer. São várias as mudanças acontecendo dentro do organismo da mulher durante muitos anos de forma gradativa, por isso, a importância dos exames de prevenção, mamografia e recorrentes orientações do autoexame das mamas (PEREIRA *et al.*, 2021; MATOS; RABELO; PEIXOTO, 2021; LILLEBORGE *et al*, 2021).

A doença pode ser diagnosticada através dos exames de mamografia, ultrassonografia, autoexame das mamas, exame clínico, ressonância magnética. Quanto mais precoce a paciente realiza os exames e detecta a neoplasia mamária, mais chances de bons prognósticos e cura, pois no início da neoplasia com o tratamento pode-se conseguir conter o tumor (BRAVO *et al.*, 2021).

Diante da problemática, levanta-se o seguinte questionamento de pesquisa: quais os fatores de risco que corroboram para o desencadeamento do câncer de mama em mulheres de meia idade? Dessa forma, objetiva-se verificar a incidência e os fatores de risco de câncer de mama em mulheres de meia idade.

Para responder à questão de pesquisa e atender o objetivo geral, foram estabelecidos os seguintes objetivos específicos, nos quais são: identificar os fatores de risco para o desencadeamento do câncer de mama, apontar a incidência do câncer de mama, descrever o papel do enfermeiro no enfrentamento do câncer de mama.

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Através da elaboração e publicação do estudo em evidência sobre os fatores de risco primordiais para o desencadeamento do câncer de mama, a população terá acesso à informação científica baseada em evidências, bem como os profissionais de saúde saberão orientar melhor esses indivíduos sobre os riscos e a prevenção da neoplasia mamária.

II. REVISÃO DA LITERATURA

2.1 Breve Histórico Do Câncer De Mama

Os primeiros registros a respeito de tumores da mama surgiram com os egípcios e gregos que tinham como uma doença incurável e os tratavam com a retirada da mama e parte do tórax como prevenção do surgimento de outros tumores as margens do anterior, este procedimento leva o nome de mastectomia radical, recebeu o nome do renomado cirurgião norte-americano William Holsted que nos meados do século XIX para o século XX, conseguiu eliminar tumores cancerígenos.

Segundo o Instituto Nacional José Alencar (2018, p. 19) a definição para mastectomia radical:"Cortes que extirpavam o tumor e uma considerável região em torno do seio, normalmente resultando na amputação de grande parte do tórax".

Os tumores nos seios eram tratados isoladamente pelos médicos cirurgiões e dificilmente chegava à cura, mesmo com as insistências de realização de cirurgias e até tratamentos medicamentosos, a doença insistia nos maiores números de óbitos na população feminina. Esta era tratada por hospitais filantrópicos e ainda por instituições religiosas descritas como Santas Casas, que cuidavam não só do físico dos doentes, mais explanavam para o espiritual (TEXEIRA; PORTO; NORONHA, 2012).

Grandes evoluções na área da medicina ocorreram como a criação de Wilhelm Conrad Röntgen, o primeiro instrumento capaz de criar imagens do interior do organismo humano a partir de raios X. Esse feito, juntamente com a descoberta de Pierre e Marie Curie, o elemento químico rádio, possibilitou o passo certo para o diagnóstico de câncer de mama. Em 1900, foi criado na Alemanha o *German Central Committe for Cancer Research*, surgindo anos depois na Inglaterra o *Imperial Cancer Research*, a doença que antes era rara começa a tornar-se um problema de saúde pública no mundo. Seis anos depois, em consequência da Primeira Conferência Internacional Contra o Câncer, foi criada a *Association Française pour l'Étude du Cancer* e, no ano seguinte, a *American Association for Cancer Research* (TEXEIRA; PORTO; NORONHA, 2012).

De acordo com os estudos de Teixeira e Neto (2020), o câncer de mama obteve visibilidade como problema de saúde pública a partir dos novos avanços tecnológicos diagnósticos, terapêuticos, e avanços no conhecimento da área médica, depois dos anos de 1940. Entretanto, foi a partir da criação do Instituto de Ginecologia da Faculdade de Medicina do Rio de Janeiro, o Serviço de Câncer Ginecológico da Cruz Vermelha e o Hospital Aristides Maltez (BA) que o câncer de mama feminino teve notoriedade no campo da saúde da mulher. No Brasil, os registros hospitalares de cânceres começaram a surgir na década de 80 pelo Hospital das Clínicas da Faculdade de Botucatu (1980-1989) (MIRRA, 2005).

Pode-se ainda destacar o desenvolvimento de quatro partes da evolução histórica do câncer de mama no Brasil: A 1ª fase é anterior ao SUS, a 2ª fase é pós-SUS, a 3ª fase é pós-consenso e a 4ª fase é a era da qualidade (PORTO; TEIXEIRA; SILVA, 2013).

A primeira fase surge com a criação da Sociedade Brasileira de Patologia Mamária, em 1959, anos depois passando a ser chamada de Sociedade Brasileira de Mastologia, obteve ênfase a carreira profissional a respeito de câncer de mama e com avanços tecnológicos diagnósticos principalmente a criação do mamógrafo, foi possível a realização da mamografia, que se tornou a escolha para rastreamento do câncer mamário em 1976, dando mais visibilidade aos pequenos tumores nos seios. Em 1984, é criado o Programa Integral da Saúde da Mulher (PAISM) visando à saúde da mulher de

forma ampla e não apenas focada no período reprodutivo (INCA, 2018).

A 1ª fase tem seu término no ano de 1986 com o surgimento do Programa de Oncologia (Pro-Onco) que nasce com o intuito de controlar e prevenir o câncer de mama no Brasil (INCA, 2021).

Em 1988, O Sistema Único de Saúde passa a ser o novo sistema de saúde do Brasil, trazendo novas possibilidades para melhoria da saúde pública do país. No ano anterior, em 1987 é iniciado um projeto piloto denominado viva-mulher que outrora visa à detecção precoce do câncer de mama e em 1996 é lançado o primeiro sistema de biopsia a vácuo (TEXEIRA; PORTO; NORONHA, 2012).

Em seguida, a fase denominada pós-SUS dá continuidade a evolução histórica a partir do ano de 2000, o INCA passou a juntar o câncer de mama ao programa de rastreamento nacional de câncer de colo de útero na perspectiva de controlar a situação do câncer de mama no Brasil. Nessa visão, no ano de 2003 é realizada uma oficina de trabalho com a participação de vários órgãos públicos, onde ficaram definidas recomendações a respeito do câncer de mama, o consenso (INCA, 2004).

Em 2005, a Política Nacional de Atenção Oncológica (PNAO) foi instituída para segurá o controle do câncer de mama no País, dando origem à fase de pós-consenso. Em conseguinte o Plano de Ação para o Controle dos Cânceres de Colo do Útero e de Mama que cria as estratégias para este fim: o aumento de cobertura da população-alvo, garantia da qualidade, fortalecimento do sistema de informação, desenvolvimento de capacitações, estratégia de mobilização social e desenvolvimento de pesquisas. No ano seguinte (2006), surge o Pacto pela Saúde propono indicadores na pactuação de metas com estados e municípios (GONÇALVES *et al.*, 2016).

O INCA, no ano de 2009, por meio do Encontro Internacional sobre Rastreamento do Câncer de Mama implementa o Sistema de Informação do Câncer de Mama (SISMAMA), e promove ainda

mais a realização da mamografia. E em 2013, é realizada a atualização pela Política Nacional para a Prevenção e Controle do Câncer na Rede de Atenção à Saúde das Pessoas com Doenças Crônicas no âmbito do Sistema Único de Saúde (SUS) SISCAN da Política Nacional de Atenção Oncológica (TEXEIRA; PORTO; NORONHA, 2012).

Em 2015, novas Diretrizes Nacionais para a Detecção Precoce do Câncer de Mama são implementadas dando ênfase nos cuidados ao câncer de mama e aos profissionais de saúde. Por fim, em 2021, os Parâmetros Técnicos para o Rastreamento do Câncer de Mama no Brasil, foram atualizados para dar uma melhor assistência à rede do Sistema Único de Saúde, o SUS. Sendo esta, por sua vez, a era de qualidade (INCA, 2021).

Apesar da história do câncer de mama estar fortemente ligada à população feminina e ser a mais afetada por esta, o câncer de mama atinge o sexo masculino em sua raridade de 1% da população. Os indivíduos que possuem histórico de câncer de mama com parentes de primeiro grau, possuem uma predisposição genética maior para a doença, bem como podem sofrer mutações nos genes BRCA1 e BRCA2 (SILVA; TOSCANI; GRAUDENZ, 2008).

2.2 Fisiopatologia Do Câncer De Mama

O câncer de mama (CM) é um problema de saúde pública atual, e é o segundo câncer que mais atinge as mulheres no mundo. É uma doença multifatorial que afeta tanto a saúde física como a saúde psicológica das portadoras. É uma doença comum entre as mulheres, segundo a estimativa do INCA (2021), estão previstos 66.280 casos novos da doença, os números de mortes são alarmantes totalizando no ano de 2020 18.032, sendo 207 homens e 17.825 mulheres.

A neoplasia mamária é definida como a proliferação celular desordenada resultante de um desequilíbrio ocasionado por fatores internos ou externos que podem ativar a proto-oncogene, ou seja, o DNA celular pode sofrer processo de mutação e desenvolver células oncogenes formando um tumor maligno ou, as células

cancerígenas ou carcinogênicas sofrem o processo de proliferação desordenadamente, porém continuam contidas (INCA, 2022).

Essa doença pode se apresentar de duas maneiras, o tumor benigno caracterizado por um tumor contido, proliferação mais lenta, de bordas regulares e um formato mais específico, ou tumor maligno que se apresenta com bordas irregulares, proliferação rápida e invasão de outros órgãos ou tecidos, sendo a forma mais agressiva do Câncer (CA) (CERQUEIRA; SILVA; OLIVEIRA, 2021)

O tipo de câncer e seu desenvolvimento são dependentes dos agentes a que foram expostos e frequência a que foram expostos. Os tipos mais comuns de CA mamários são o carcinoma ductal invasivo que se desenvolve nos ductos lactíferos e o carcinoma lobular infiltrante, consecutivamente. Esse tipo de câncer está localizado no quadrante superior externo e se desenvolve nos ductos mamários (COSTA *et al*, 2021)

Os sinais e sintomas da doença são nódulos indolores e palpáveis nos seios, saída de secreções pelo mamilo, pele do seio aspecto de casca de laranja. Vale ressaltar a importância de a mulher conhecer o seu próprio corpo, principalmente as possíveis alterações no período de pós menopausa, para que esta esteja atenta aos primeiros sinais de câncer de mama (SANTANA *et al*, 2021).

2.3 Mulheres Em Período Pós-Menopausa E Os Fatores De Risco Para Desenvolvimento Da Neoplasia Mamária

As mulheres em meia idade (45-50 anos de idade e acima dos 50 anos) apresentam-se em período pós-menopáusico, o que relacionado a outros fatores pode desenvolver a neoplasia mamária com maior facilidade em relação às mulheres pré-menopausadas e/ou jovens (PROCÓPIO, 2022; INCA, 2018).

Diversos fatores estão entrelaçados para o aumento do desenvolvimento do câncer de mama, portanto vale destacar que além da idade, o histórico familiar e pessoal (história familiar de câncer, alteração genética), características

reprodutivas e hormonais (menarca precoce antes dos 12 anos de idade, primeira gestação após os 30 anos de idade, menopausa tardia, uso de terapia hormonal) e fatores comportamentais / ambientais (obesidade, ausência de atividade física, etilismo, tabagismo) (INCA, 2021; LILLEBORGE, *et al.*, 2021).

2.3.1 Idade

A idade é um fator crucial para o desenvolvimento do câncer, em mulheres na pós-menopausa, devido aos fatores hormonais e um funcionamento mais lento do organismo. A Meia idade é descrita como idade entre 45 e 55 anos de idade e está situada no período de climatério (SIMÕES *et al*, 2022; MINISTÉRIO DA SAÚDE, 2009).

2.3.2 Histórico Familiar E Pessoal

O câncer de mama possui maiores chances de se desenvolver quando os indivíduos têm relatos de casos de câncer de mama ou ovariano na família e o grau de parentesco é próximo (ALMEIDA, 2021).

As características genéticas estão relacionadas a dois tipos de genes que os indivíduos principalmente do sexo feminino podem herdar, o BRCA1 e o gene BRCA2, e ainda um grupo de enzimas (GST1- Glutationa S-transferase Mu1, GSTT- Glutationa S-transferase teta-1 e GSTP- Glutationa S-transferase P1) responsáveis pela catalização de compostos genotóxicos e citotóxicos, podem ser suprimidos fazendo com que não haja metabolização celular e haja acúmulo dessas substâncias na célula ocasionando assim lesão celular (CASTRALLI; BAYER, 2019).

2.3.3 Fatores Reprodutivos

As mulheres em idade menopáusica e pós-menopáusica possuem uma queda na produção de alguns hormônios, e um desses hormônios é dado o nome de estrogênio que influência no organismo da mulher de forma significativa. A menarca precoce anterior aos 12 anos de idade é um fator considerado para o desenvolvimento do câncer de mama e está

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diretamente ligado a fatores hormonais, assim como a gestação tardia a partir dos 30 anos para o primeiro filho ou nunca ter estado gesta e a menopausa tardia considerada após os 55 anos de idade (MARTINS; PINHEIRO, 2021).

Com o avançar da idade advém o período de climatério marcado pela transição do período fértil para o término desse período, que está previsto entre 45 e 55 anos de idade. Nessa fase, acontecem muitas mudanças no organismo da mulher, como alterações vasomotoras, cardiovascular, óssea e no sistema urogenital, nas paredes vaginais, por exemplo, com a pouca produção de estrogênio à ressecamento das mesmas, sendo muitas vezes necessitado uma reposição desses hormônios para o alívio dos sintomas da menopausa (SIMÕES *et al*, 2022).

Em contrapartida, a reposição hormonal não está indicada para as mulheres no período pós-menopáusico ou menopáusico, pois a reposição do hormônio afeta a proliferação celular, quando isso acontece às células cancerígenas ou carcinogênicas são multiplicadas aumentando as chances do desencadeamento câncer de mama (MARTINS; PINHEIRO, 2021).

2.3.4 *Fatores Comportamentais E Ambientais*

Existem diversos fatores que influenciam no desenvolvimento do câncer de mama, pode-se destacar a obesidade, ausência de atividade física, etilismo e tabagismo, sendo fatores modificáveis e reversíveis. A obesidade é conceituada como o excesso de tecido adiposo no corpo do indivíduo que não está correspondente à sua altura. É considerado obeso ou sobrepeso um indivíduo com o Índice de Massa Corporal maior (IMC) ou igual a 30 kg/m2 e com os valores consecutivos entre 25 e 29,9 kg/m² e como magras pessoas com IMC abaixo de 25 kg/m² (FEBRASGO, 2019). De acordo com os estudos de Sanger (2018), a obesidade traz um alto risco para o desenvolvimento do câncer de mama principalmente em mulheres no período pós-menopáusico, pois há um acúmulo excessivo de tecido adiposo no corpo da mulher.

O tecido adiposo desempenha uma função no organismo das mulheres em período pós-menopáusico diferente das em idade jovem, sendo responsável pela produção hormonal, o que pode alterar o ciclo fisiológico das células cancerígenas fazendo com que as mesmas se desenvolvam no tecido mamário e desenvolva-se inflamação crônica (NOGUEIRA *et al.*, 2020).

A inatividade física caracterizada pelo sedentarismo leva aos indivíduos ficarem sobrepesos ou obesos. Ao não queimar as calorias ganhas durante o dia, há o acúmulo de tecido adiposo contribuindo negativamente para o desenvolvimento do câncer de mama (CARVALHO; PINTO; KNUTH, 2020).

Outro ponto, a ser abordado, é que o organismo ou sistema imune não se fortalecem com atividade física diária, isso aliado a uma alimentação inadequada, contribui no desencadeamento do câncer de forma ainda mais rápida (SOUZA; MOREIRA, 2020).

As bebidas alcoólicas são um risco para a saúde dos indivíduos, com destaque para a população feminina, principalmente em período de pós-menopausa. O etanol é acetaldeído, que é carcinogênico, provoca o aumento de produção de estrogênio, além de sintetizar substâncias reativas de oxigênio causando danos ao DNA humano, sendo possíveis mutações nas células. Agem ainda na membrana plasmática aumentando sua permeabilidade às células cancerígenas (OLIVEIRA *et al.*, 2019).

O hábito de fumar é prejudicial à saúde respiratória e da população no geral, é considerada fortemente uma ameaça para desencadear o CA. Todavia, segundo alguns estudos ainda não se sabe ao certo como o tabagismo age no organismo (MARTINS; PINHEIRO, 2021).

III. PROCEDIMENTOS METODOLÓGICOS

O estudo é uma revisão integrativa da literatura, descritiva e exploratória. As revisões integrativas consistem em reunir artigos já publicados sobre um assunto determinado, possibilitando uma síntese desse conhecimento científico, gerando então um novo conhecimento a partir desses estudos (BOTTELO; CUNHA; MACEDO, 2011).

O estudo de revisão integrativa possui seis etapas para sua construção, as quais são descritas a seguir: a) identificação do tema e seleção da hipótese ou questão de pesquisa para a elaboração da revisão integrativa; b) critérios para inclusão e exclusão de estudos/amostragem ou pesquisa de literatura; c) definição das informações a serem extraídas dos estudos selecionados/categorização dos estudos; d) avaliação dos estudos incluídos na revisão integrativa; e) interpretação dos resultados e, f) apresentação da revisão/síntese do conhecimento (SOUZA *et al.*, 2017).

Os estudos descritivos e exploratórios são estudos que visam facilitar o entendimento do pesquisador sobre o instrumento a ser estudado, possibilitando ao mesmo formar sua própria ideia e entendimento, ou seja, permite conhecer o instrumento como se apresenta o seu significado e o contexto no qual se encontra (PIOVESAN; TEMPORINI, 1995).

A efetivação da busca de dados se deu nas seguintes bases de dados: *Literatura Latino-Americana e do Caribe em Ciências da Saúde (LILACS), Sistema Online de Busca e Análise de Literatura Médica (MEDLINE), National Center for Biotechnology Informacion (PUBMED).* Os termos-chave utilizadas para a construção dessa pesquisa estão inseridos nos Descritores em Ciências de Saúde (DeCS), as quais são: "Neoplasias de Mama" "AND" "Pessoa de Meia-Idade" "AND" "Fatores de Risco" "Pós-Menopausa", nos idiomas português e inglês, cruzando com os operadores booleanos AND e OR.

Os critérios de inclusão para a seleção de artigos foram: artigos completos disponíveis gratuitamente; artigos originais e revisões sistemáticas da literatura; nos idiomas português, inglês e espanhol, publicados entre 2018 e 2022, com vistas à obtenção de literatura atualizada. Foram encontrados 122 artigos, sendo selecionados 08 artigos para compor o estudo. Os critérios de exclusão visam dispensar artigos que não atendiam aos objetivos dessa pesquisa ou sua aproximação ao tema. A coleta de dados ocorreu nos meses de fevereiro a dezembro de 2022.

Na apresentação e discussão dos resultados visam-se analisar minuciosamente os conteúdos das publicações utilizados nessa pesquisa, investigando-as, explorando e compreendendo suas conclusões, interpretações e, por fim, ar os resultados.

Diante do exposto, é notória a contribuição das publicações enriquecendo a elaboração desse estudo com os resultados e conclusões obtidos a respeito do câncer de mama em mulheres de meia idade, e os fatores de risco desta patologia.

IV.   RESULTADOS E DISCUSSÕES

Nesta seção serão apresentadas as publicações inclusas para a elaboração do estudo, sendo descritas e analisadas minuciosamente. Com o cruzamento dos descritores de saúde nas bases de dados utilizadas nesse estudo, sendo encontrada uma amostra inicial de 122 artigos, após a aplicabilidade de filtro e critérios de exclusão, foram selecionados 08 estudos, sendo estes estudos de revisão sistemática, meta-análise, coorte e randomizados.

A seguir, será apresentado o fluxograma que descreve o processo metodológico de busca na literatura nas bases de dados e sua seleção para fazerem parte do presente estudo. E em seguida o quadro sinóptico dos resultados.
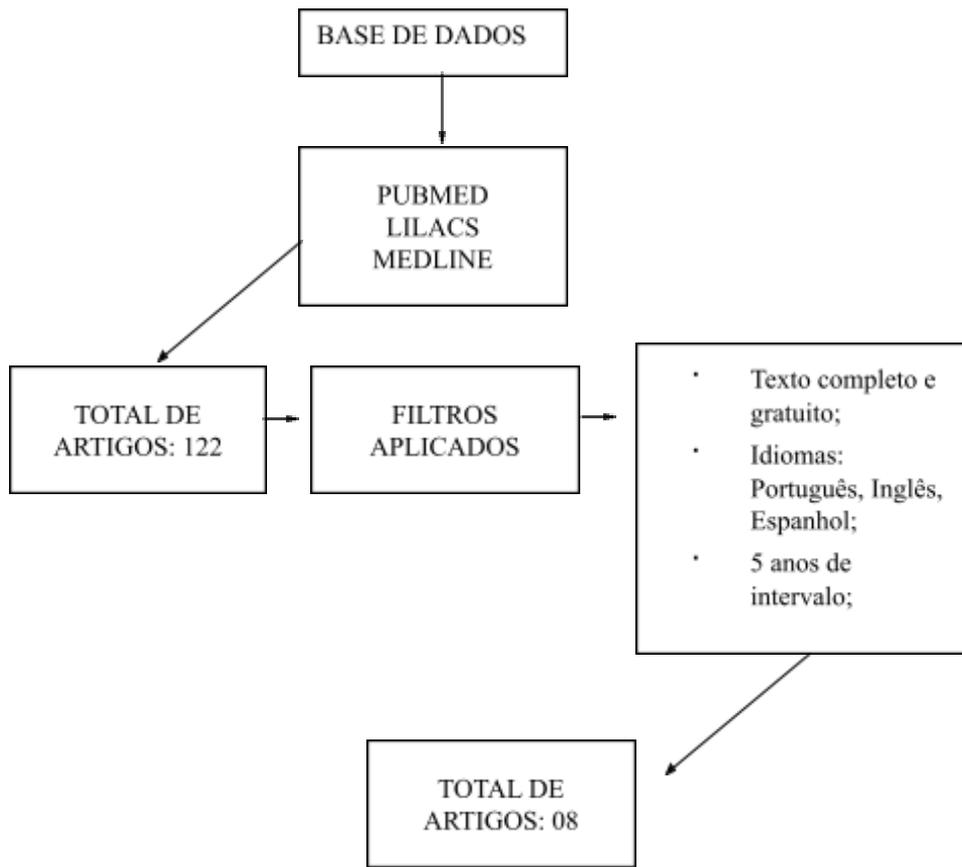
Fluxograma 1: Processo metodológico para seleção dos artigos

Quadro 1: Quadro Sinóptico dos Resultados

Artigo	Base de Dados	Autor/Ano	Título	Revista	Objetivo
1	Medline	LEE *et al.,* (2021)	Trabalho sedentário e risco de câncer de mama: uma revisão sistemática e meta-análise	*Journal off occupation Health*	Avaliar quantitativamente a contribuição do trabalho sedentário para o risco de câncer de mama usando artigos de pesquisas completos.
2	Pubmed	AKDENIZ *etal.,* (2021)	O impacto do estilo de vida e fatores reprodutivos no risco de um segundo novo câncer primário na mama contralateral uma revisão sistemática e meta-análise	*Springer Link*	Avaliar o impacto do estilo de vida e dos fatores reprodutivos no risco de CBC em estudos populacionais de câncer de mama.
3	Lilacs	Grupo colaborativo sobre fatores hormonais no câncer de mama (2019)	Tipo e momento da terapia hormonal da menopausa e risco de câncer de mama: meta-análise de participante individual da evidência epidemiológica mundial	*The Lancet*	Avaliar os riscos associados a tipos específicos de MHT em relação ao tempo de uso.

4	Pubmed	CHEN et al., (2019)	Atividade e risco de câncer de mama: uma meta-análise de 38 estudos de coorte em 45 relatórios de estudo	*Value in Health*	Avaliar e quantificar a associação entre atividade física (AF) e risco de câncer de mama.
5	Pubmed	SHAMSHIA *et al.*, (2019)	Fatores de câncer de mama no Irã: uma revisão sistemática e meta-análise	*Horm Mol Biol Clin Investig*	Realizar uma revisão sistemática e meta-análise com foco na epidemiologia dos fatores de risco do câncer de mama no Irã.
6	Pubmed	KOUR *et al.*, (2019)	Análise de fatores de risco para câncer de mama em mulheres em pré e pós menopausa de Punjab, índia.	*Asian pacific Journal of câncer prevention*	Investigar a etiologia do câncer de mama usando vários índices de obesidade e outros fatores epidemiológicos entre pacientes com câncer de mama residentes na cidade de Amritsar e arredores.
7	Pubmed	SINGHAVI *et al.*, (2020)	Álcool e risco de câncer: uma revisão sistemática e meta-análise de estudos indianos prospectivos	*Indian Journal of public Health*	Determinar a relação entre álcool e câncer na Índia por meta-análise.
8	Pubmed	LILLEBOR GE *et al.*, (2021)	O câncer de mama pode ser interrompido Fatores de risco modificáveis de câncer de mama em mulheres com lesão benigna ou pré-maligna prévia	*IJC Internation al of Journal Cancer*	Estimar a associação entre os fatores modificáveis atividade física, IMC, consumo de álcool, tabagismo, uso de TH e o risco de câncer de mama em mulheres com lesão benigna, hiperplasia com atipia ou carcinoma in situ detectado após a participação no Breast Screen Noruega.

Fonte: Dados da pesquisa, 2022

Os resultados demonstrados acima serão descritos e discutidos, revelando a perspectiva de outros autores sobre o câncer de mama e seus fatores de risco em mulheres em período pós-menopáusico. Conforme o estudo um, realizado por Lee *et al* (2021), intitulado "Trabalho sedentário e risco de câncer de mama: uma revisão sistemática e meta-análise" que possui por objetivo avaliar quantitativamente a contribuição do trabalho sedentário para o risco de câncer de mama usando artigos de pesquisas completos, aborda que quanto maior o tempo que o indivíduo passa sentado durante dias, está ligado diretamente ao ganho de peso em decorrência do sedentarismo e estilo de vida adotado.

Os autores explicitam que devido ao comportamento sedentário houve um aumento significativo do tecido adiposo no organismo, resistência à insulina, inflamação sistêmica, hormônios sexuais e um aumento da densidade mamária. Esse acúmulo de tecido desencadeia as carcinogênicas, elevando os níveis de estrogênio nas mulheres em período pós-menopáusico. Os mesmos ainda destacam que a alteração dos hormônios sexuais, é uma alteração no ciclo menstrual e na gordura corporal das mulheres tanto em período pré-menopáusico como no pós-menopáusico, sendo resultados da inatividade física e sedentarismo.

Outro estudo que deixa claro sobre o fator de risco obesidade é o de kour *et al* (2019), destacando através do estudo de caso-controle, que a obesidade é um risco em mulheres na pós-menopausa e a paridade como risco para as mulheres em pré-menopausa. Relata ainda que mulheres na pós-menopausa com IMC elevado, sendo de sobrepeso, obesas, maior risco, já mulheres na pré-menopausa com 3 ou menos de 3 filhos apresentaram maior risco em relação àquelas em pós-menopausa.

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É importante salientar que há diversos fatores de risco para o desenvolvimento de câncer de mama em mulheres de meia idade, sendo destaque o sedentarismo que leva à obesidade e causa alterações hormonais. De acordo com Akdeniz *et al* (2021), que traz por título em seu trabalho "O impacto do estilo de vida e fatores reprodutivos no risco de um segundo novo câncer primário na mama contralateral uma revisão sistemática e meta-análise" descreve que mulheres em período pós menopausa com um IMC elevado é um fator de risco para o câncer de mama reafirmando o estudo abordado por Lee e colaboradores. Dessa forma ressalta-se que o estilo de vida, tais como o uso de álcool, paridade primária com idade avançada traz um risco inefável para CM.

Em relação a uso de álcool como fator de risco Singhavi *et al* (2020), deixa explícito em suas conclusões que o uso de álcool, além de provocar risco à saúde da população, trazendo outras doenças para os indivíduos como doenças infecciosas, mentais, lesões e as doenças não transmissíveis, como corrobora significativamente para o câncer de mama. Não está evidência a quantidade e ocorrência que o álcool necessita para causar o câncer, porém seu componente acetildeído é altamente carcinogênico, metabólito do etanol. Com o seu acúmulo no organismo acaba provocando prejuízos a enzima responsável por seu metabolismo, fazendo com que haja altos níveis de estrogênio e androgênio nas mulheres em susceptibilidade ao CM. O álcool provoca lesão no tecido do epitélio, desencadeando ação inflamatória e o processo de carcinogênese.

O trabalho desenvolvido pelo Grupo colaborativo sobre fatores hormonais no câncer de mama (2019) sob o título "Tipo e momento da terapia hormonal da menopausa e risco de câncer de mama: meta-análise de participante individual da evidência epidemiológica mundial" aborda principalmente a terapia de reposição hormonal para as mulheres em idade de menopausa como alto risco para o CM. Mostra que as mulheres que tiveram início do uso da terapia na menopausa o risco é maior em relação àquelas que nunca usaram a terapia.

Alegam os autores que, quanto maior o tempo de uso da terapia hormonal e seu início na menopausa, maior o risco para doença de forma invasiva, sendo destaque o risco para estrogênio-progestagênio do que para as preparações somente de estrogênio para o uso da terapia hormonal.

As mulheres em meia idade passam pelo período de transição da fertilidade para ausência da mesma e fim dos ciclos menstruais, nestes momentos o organismo começa a mostrar sinais e sintomas da baixa síntese de hormônios estrogênio e progesterona, uma redução na forma do organismo trabalhar, deixando notório o processo de envelhecimento.

O estudo do grupo colaborativo sobre fatores hormonais no câncer de mama corrobora que ponderando que entre as mulheres na pós-menopausa nos países ocidentais, o câncer de mama é responsável por cerca de três quartos de todos os casos e óbitos por câncer de mama, e que a atividade estrogênica pós-menopausa é um forte determinante da incidência de neoplasias mamárias.

Esse, por sua vez, visa alcançar seus objetivos, tais como, avaliar os riscos associados a tipos específicos de MHT em relação ao tempo de uso, sendo observado que a incidência para o câncer de mama ou seu risco está diretamente ligada à idade que as mulheres estão e fazem o uso da terapia de reposição hormonal. Quanto se mais envelhece mais se necessita de reposição hormonal, todavia é necessária cautela no uso dessa terapia, já que, está associado a um período pós-menopausa e IMC elevado, ou seja, mulheres com sobrepeso ou obesas correm um maior risco de desenvolver o CM.

De acordo com o autor Chen *et al* (2019) no artigo "Atividade e risco de câncer de mama: uma meta-análise de 38 estudos de coorte em 45 relatórios de estudo incrementa com seu estudo que fatores como primariedade tardia, idade da menarca, fatores hormonais interferem e ajuda a promover o desencadeamento de CM em mulheres de meia idade.

O estudo evidência que a atividade física promove um melhor condicionamento para o organismo, regulando os níveis de gordura, logo, ajuda na redução do risco de CM. Não explicita a frequência e duração dessas atividades físicas, porém deixa nítido que sua realização reduz a obesidade e as chances de desenvolver a doença descrita.

A quinta publicação selecionada sob autoria de Shamshian *et al.*, (2019) "Fatores de câncer de mama no Irã: uma revisão sistemática e meta-análise" explana suas descobertas, fatores como histórico familiar, TH, fumantes passivos, gravidez tardia, aborto, consumo de doces e genótipo Arg/Arg, indicaram associação e maior chances de desencademanto de CM. Todavia, fatores de menarca tardia, nuliparidade, 13-24 meses de amamentação, exercícios diários e consumo de vegetais mostraram servir como prevenção para o desenvolvimento dessa doença.

Na mesma linha de pesquisa, destaque-se Lilleborge *et al* (2021) com o "câncer de mama pode ser interrompido? fatores de risco modificáveis de câncer de mama em mulheres com lesão benigna ou pré-maligna prévia", onde a mesma aborda, que a Terapia hormonal, obesidade, alcoolismo, tabagismo, histórico familiar e histórico reprodutivo se encontrou associado com o aumento de risco de CM para mulheres em período de pós-menopausa e mulheres com lesão pré-maligna ou benigna. Os autores recomendam que com a atividade física, controle de peso e a redução do alcoolismo, adotando um estilo de vida mais saudável e seguro, essas mulheres reduziram as chances de desenvolver o câncer de mama.

Alcança em seu objetivo estimar a associação entre os fatores modificáveis atividade física, IMC, consumo de álcool, tabagismo, uso de TH e o risco de câncer de mama em mulheres com lesão benigna, hiperplasia com atipia ou carcinoma in situ detectado após a participação no Breast Screen Noruega.

Todos os fatores de risco encontrados, através da união desses estudos, deixam claro que, a população precisa ser assistida, sendo primordial um trabalho de prevenção através da mamografia precoce e exame das mamas. Os profissionais de Saúde, principalmente o enfermeiro devem orientar a população alvo sobre esses riscos que corriqueiramente estão expostas.

Saber reconhecer sinais e sintomas da doença é imprescindível para procurar a assistência à saúde da mulher e até masculina. A mamografia como ação preventiva é o ideal, o rompimento com tabus do medo se faz necessário, isso só é possível através do conhecimento. O autoexame das mamas e o exame das mamas são uma alternativa adequada para perceber possíveis alterações. Por fim, se detectadas alterações nas mamas, um possível diagnóstico precocemente da doença, aumenta as chances de uma de um tratamento eficaz e uma recuperação da doença.

V. CONCLUSÃO

Conforme o exposto pode-se inferir que os fatores de risco encontrados na literatura, sendo: menarca tardia, paridade tardia, tabagismo, alcoolismo, terapia hormonal, sedentarismo que leva a obesidade, a idade (período de pós-menopausa), histórico familiar da doença, possuem uma associação forte para o risco de desenvolvimento de câncer de mama.

O estudo trouxe evidências que de fato a população feminina, é o grupo mais acometido por esse tipo de doença, principalmente no período de pós-menopausa atrelado a outros fatores já descritos no estudo.

Os fatores de riscos apresentados são preocupantes, as mulheres em diversas ocasiões deixam a paridade para os 30 anos de idade, o que pode ocasionar má formação no bebê e risco para a saúde da gestante. O estilo de vida adotado por grande parte da população é um estilo de vida sem a prática de exercícios físicos, o sedentarismo e sobrepeso, alimentação inadequada, além do consumo de álcool e tabagismo.

Esses fatores acabam propiciando o desencadeamento mais rápido do câncer de mama em indivíduos que possuem uma predisposição genética, com a alteração na BCR1 e BCR2, que

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acontecem quando se tem parentes de primeiro grau que já tiveram ou têm o câncer.

A prevenção é indispensável, a orientação da população sobre a prática de exercícios físicos, evitarem uma alimentação rica em gorduras, a adoção de um estilo de vida saudável, bem como orientar as mulheres sobre o período de climatério e a reposição hormonal, que nem sempre será indicado, pois, os estudos trazidos neste trabalho expuseram o risco que as mesmas possuem ao uso prolongado da terapia.

Todo o processo de envelhecimento e um ritmo mais vagaroso do organismo contribuem para o processo de desenvolvimento do câncer de mama. Dessa maneira, os objetivos propostos neste trabalho foram alcançados, visto que através da revisão literária foi possível reunir o conhecimento amplo sobre o tema em questão.

Espera-se que este estudo contribua para a compreensão da população e dos profissionais de saúde para que, os tais, através do conhecimento desta literatura adquirida, orientem e trabalhem em cima da prevenção do câncer de mama principalmente em mulheres no período de pós-menopausa.

A um conteúdo amplo sobre o câncer de mama na literatura, mas faltava um trabalho que reunisse todos os fatores de risco para o câncer de mama nas mulheres de meia idade que se encontram no período de pós-menopausa. Este trabalhado é inovador e traz para a saúde pública um conteúdo reunindo os estudos recentes, contribuindo para a elaboração de conhecimento científico confiável e um viés propício para propagar os principais fatores de risco para desencadear o câncer de mama.

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