Analysis of Biological Samples Necroscopic Reports From The Death Verification Service Of The State Of Tocantins, Brazil

Abstract*—Analyze, in the necroscopic reports of the Death Verification Service of the State of Tocantins (SVO- TO), the records of biological samples collected for histopathological examination and records of autolysis in histopathological results and correlate them with records of causes of mortality and morbidity. Cross-sectional observational analytical study conducted in 494 autopsy reports completed and filed in SVO-TO, Brazil, between 2012 and 2016. Records of the number of biological samples collected for histopathology, number of autolysis, number of causes of mortality and number of causes of morbidity were extracted and identified. For the analysis of the relationship between the variables, descriptive and analytical statistics were used in SAS SYSTEM software. The mean number of mortality records was 5.72 ± 2.42 (CV 42.32%), causes of morbidity: 0.2 ± 0.5 (CV 251.46%), number of biological samples collected: 2.66 ± 1.13 (CV 42.59%), number of autolysis: 1.74 ± 1.05 (CV 60.06%). The number of mortality and morbidity diagnoses recorded in SVO reports increases the higher the number of samples collected by necropsies physicians. The number of biological samples collected by necropsy positively impacts the number of causes of mortality and morbidity. Collecting more than seven tissue samples by necropsy does not impact the number of causes of mortality and morbidity. The low numbers of autolysis records suggest efficacy in the collection of biological samples in SVO-TO.*

Keywords- histopathological results, Necropsy, Vital statistics, Epidemiological surveillance

1. Introduction

The clarification of the cause of death is based on the principle of information as a subsidy to obtain appropriate actions in each health area[1]. In Brazil, the Mortality Information System (SIM), among other functions, captures and processes national data on morbidity and mortality, producing vital statistics, epidemiological, social and demographic analyses, allowing establishing a population epidemiological profile granting public health management[2–6].

In 2006, a national network of Death Verification Service was created by Ordinance MS/GM n°. 1,405, as an epidemiological surveillance instrument to improve information on national mortality and morbidity, with competencies related to the development of a set of actions aimed at clarifying the cause of death, in addition to the detection and investigation of any suspected or confirmed disease of compulsory notification attended in the hospital, using national, state and municipal epidemiological surveillance standards as an epidemiological surveillance tool for epidemiological surveillance for improve information on national mortality and morbidity[6].

In 2007, with the creation of the national SVO network, the Tocantins State Death Verification Service (SVO-TO) regulated by the state ordinance June 119, 2007[7–8], was implemented in the State of Tocantins. Headquartered in Palmas and with a branch in Araguaína, the SVO- TO can be triggered by physicians by completing a request form for necropsy and family authorization for autopsy with the signature of the Free and Informed Consent Form (TCLE[9]).

SVO pathologists elucidate causes of ill-defined natural deaths, with or without medical care, through necroscopic examinations[6]. Necropsy enables a clear diagnosis of causes of death and related mechanisms, constituting an important instrument for assessing medical care quality[10]. After necropsy with the elucidation of the causes of deaths, death certificates (OD) and necroscopic reports are issued by SVO-TO[7] physicians.

To make OD and necroscopic reports in The SVO-TO, physicians have a histopathological analysis of biological samples collected during autopsy anatomy pathology. However, some records of results of histopathological examinations returning from the laboratory exhibit only autolysis. Autolysis is a phenomenon of tissue decomposition that may be associated with inadequate procedures for collecting, packaging and transporting biological samples from the necropsy.

The presence or absence of autolysis in the records of results of histopathological scans of the SVO-TO may directly or indirectly alter the number of records of diagnoses of causes of mortality and morbidity in necroscopic reports. The impact of histopathological results of biological samples on diagnoses of causes of mortality and morbidities emitted in necroscopic reports is unknown in SVO-TO.

Analyzing the number of records of histopathological results by necropsy, especially the quality of the records with the presence or absence of autolysis from the analysis of biological samples, may contribute to the improvement of the protocols of collection, packaging, and transport of biological samples in the SVO-TO.

Establishing the relationships between the quantity and quality of records of histopathological results with the number of records of causes of mortality and morbidity in necroscopic reports may direct necropsy protocols. The costs of necropsy can be resolved in the possibility of determining a consensus regarding the number of samples collected in each necroscopic test in the SVO-TO.

The present study will indicate the impact of SVO-TO on the necroscopic investigation of deaths due to ill-defined causes and will guide mechanisms for standardization of operational procedures, promoting cost reduction in the production of reliable vital statistics for the Mortality Information System.

Thus, the objective of the study was to analyze in the necroscopic reports of the Death Verification Service of the State of Tocantins (SVO-TO), the records of biological samples collected for histopathological examination and records of autolysis in histopathological results and correlate them with records of causes of mortality and morbidity.

2. Materials and methods

The cross-sectional observational analytical study performed in necropsy reports completed by pathologist physicians between 2012 and 2016 and filed in the Death Verification Service of the State of Tocantins (SVO - TO) based in the capital, Palmas, Brazil (figure 1).

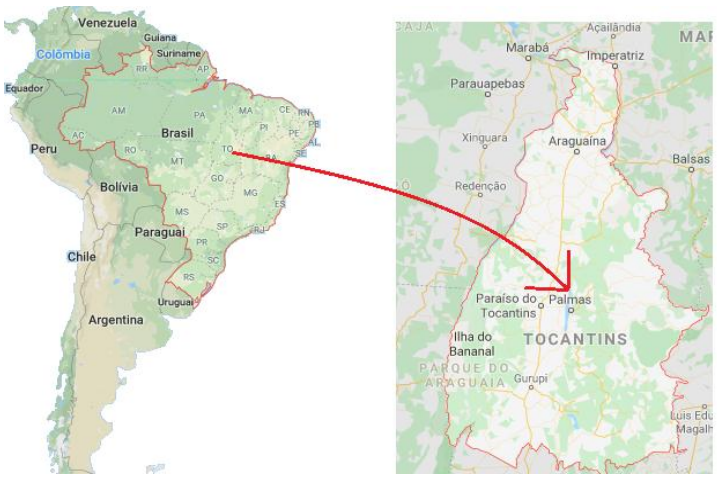

Fig 1: Brazil and Tocantins State, the capital Palmas-Location of SVO-TO. Fonte:adapted-Google earth, 2019.

According to the Brazilian Geographic and Statistics Institution (IBGE, 2019), the total number of population is measured of 299.127 habitants in the Palmas city and 1.572.866 in the Tocantins State. The reports were duly dispatched to bereaved relatives and public entities dealing with surveillance of state and municipal deaths. The contact of the researchers was restricted exclusively to the Files of the SVO, after the proper authorization of the technical responsible for the service. All and all information on the identity of necropsy patients, physicians, necropsies technicians and bereaved family members were preserved, according to the ethical precepts recommended in resolution nº466/2012/CNS/Brazil. This study is part of a research project submitted to the Brazil platform and approved by the Research Ethics Committee by substantiated opinion number: 2708612. (ANNEX 1)

Identified the number of necroscopic reports that met the inclusion and exclusion criteria, the variables analyzed were records on the number of biological samples collected by necropsy for histopathological examination, on the quality of biological samples, using as a quality indicator the presence or absence of autolysis in histopathological results, records on the number

diagnoses of causes of mortality and on the number of morbidity diagnoses.

In SVO-TO, each necropsy generates only a single necroscopic report. During necropsy, performed by necropsies physicians and auxiliary technicians, the pathological examination is followed by the collection of tissue samples that are packed by technicians in 10% formaldehyde and sent to a third-party external laboratory for histopathological examination. The result of the histopathological examination is a product of microscopic analysis of tissue samples collected by the Necropsist physician. In from possession of histopathological results, the necrophilic physician concludes the necroscopic report correlating clinical, imaging, pathological findings, histopathological, immunohistochemical and other complementary pathology tests Clinic.

The necroscopic reports of the SVO-TO are standardized in 2012 in cooperation with a team of technicians from the Ministry of Health (MS). Information on the necroscopic study of the patients examined is recorded in the eighty-nine variables. The eighty-nine variables are organized into seven specific fields: identification, history, previous history, necroscopic examination, collection of biological samples, completion, and discussion.

The recorded information that will be analyzed on the number of biological samples and histopathological diagnoses are contained in the field: a collection of biological samples from the necroscopic report. In this field, the tissues were removed from the Necropsist physician for histopathological examination and which histopathological laboratory results sent by the outsourced laboratory for each collected organ were removed from the laboratory.

The records on diagnoses of the causes of mortality and morbidity are also found in the field completion of the necroscopic report, arranged in a manner analogous to that found in death certificates. The conclusion field is divided into question death part 1, with records on diagnoses of mortality, and causes death part 2, with records on diagnoses of morbidities.

The study included necroscopic reports of the SVO-TO in Palmas, Brazil, elaborated completed and made available to family members and entities dealing with death surveillance. Necroscopic reports that exhibited recorded information on the number of biological samples collected, histopathological diagnoses, causes of mortality and causes of morbidity, from 2012 to 2016. Necroscopic reports that did not belong to the SVO-TO in Palmas, Brazil, uncompleted or prepared out of the period from 2012 to 2016, reports that were not made available to family members or entities dealing with death surveillance and reports, were excluded from the study. Who did not exhibit recorded information on the number of biological samples collected, histopathological diagnoses, and causes of mortality.

2.1. Data Analysis

The collected data were organized in an Excel spreadsheet® 2013, and the variables studied and in the rows were arranged in the columns the identification of each sample (n) according to the initials of the name, age, and gender.

For the verification of Normality, SAS software (SAS, 2013) was used through the Kolmogorov-Smirnov (K-S) and Shapiro-Wilk (S-W) tests at 5% significance. These tests provide the specimen test value (value-p, p-value or significance), which can be interpreted as the measure of the degree of agreement between the data and the null hypothesis (H0), with H0 corresponding to the Normal distribution. The lower the p-value, the lower the consistency to accept the null hypothesis. After determining normality, a Variance Analysis (ANOVA - one way) was implemented using the Wilcoxon and Kruskal-Wallis ranks test, which allowed us to test the effect of the number of samples collected and recorded in necroscopic reports of SVO-TO with the number of records on the causes of mortality and morbidity. Thus, each Yij observation, which represents the SAH values, can be decomposed according to the model below:

$$Y_{ij} = \mu + V_i + \varepsilon_{ij}$$

In which::

Yij is an observation of the i-th treatment in the j-th experimental unit;

μ is the constant effect (general average);

$\mathbf{V}_i$ is the effect of the i-th variable;

ε_{ij} is the effect of random error associated with i-ésima variable *i* with error *j*.

Additionally, the correlation analysis was applied to identify the degree of the linear relationship between the variables of interest, in the case of the present study, the records of the number of morbidity and mortality with the amount of sample and the number of autolysis Identified. The model that will be adopted in this analysis can be represented as:

$$r = \frac{\sum XiYi \; x \; \frac{(\sum XiYi)}{n}}{\sqrt{\sum Xi^2 - \frac{(\sum Xi)^2}{n}} \; x \; \sqrt{\sum Yi^2 - \frac{(\sum Yi)^2}{n}}}$$

Fig. 1: Correlation analysis.

In which:

r = represents the correlation coefficient between the variables used in the analysis;

$\sum$ **XiYi** = sum of the product of the two variables used in the analysis;

n = number of database observations;

$\sum X_i^2$ = sum of the values of the variable X squared;

$\sum Y_i^2$ = sum of the values of the variable Y squared;

The results generated in the analyses will be organized into tables and charts for better visualization.

3. Results and Discussion

According to the DataSUS platform, Brazil, the most common causes of death in Palmas in 2017 include with those numbers, Diabetes mellitus with 134 deaths, Hypertensive Disease with 153, Ischemic Heart Diseases, with 175, Cerebrovascular Diseases, with 153, Chronic Lower Airway Diseases, with 101, Transport Accidents, with 152 and Aggressions with 149. Between 1998 and 2014, proportional mortality from ill-defined causes fell 88.5% in Tocantins and 88.1% in Palmas, Brazil.

We studied 494 necroscopic reports, with 1314 causes of mortality (N1) recorded with a mean of 2.66 ± 1.13 (C.V. 42.59%). The minimum value of N1 was 1, maximum value: 7, 1st Quartile (Q1): 2, Median: 2, 3rd quartile (Q3): 3, fashion: 2, asymmetry: 0.83, kurtosis: 0.92, defining a distribution curve. Most reports presented 2 records of mortality diagnoses (Figure 2).

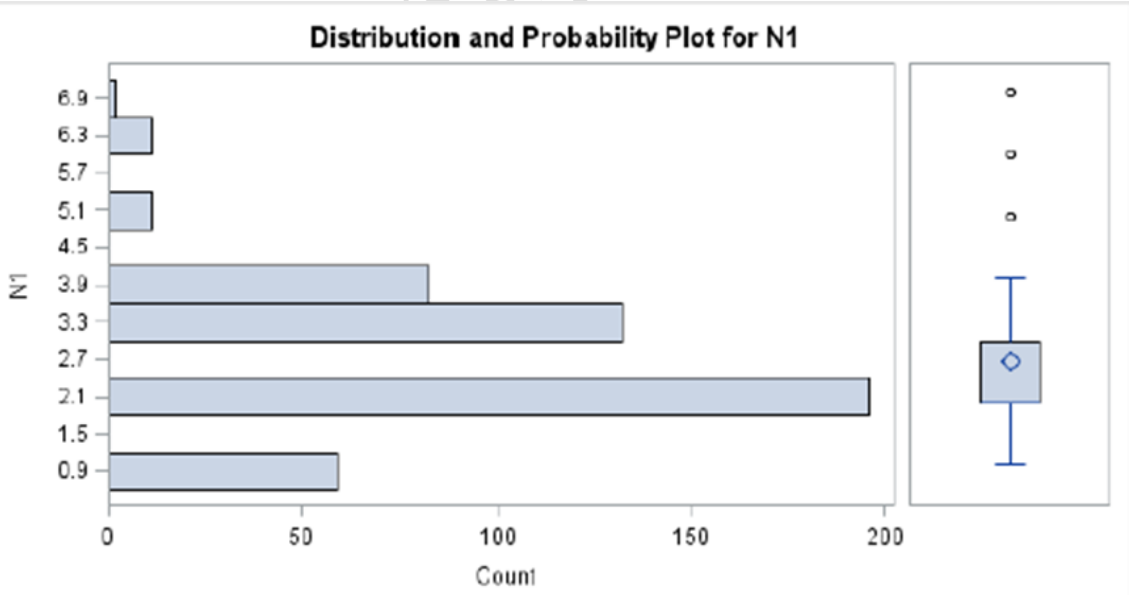

Fig. 2: Distribution and probability for records and causes of mortality (N1).

The number of records of causes of morbidities (N2) was 861 with an average of 1.74 ± 1.05 (C.V. 60.06%). The minimum value was 0, maximum value: 6, 1st Quartile (Q1): 1, Median: 2, 3rd quartile (Q3): 2, fashion: 2, asymmetry 1.5, kurtosis: 4.0, defining a leptokurtic distribution curve. Most reports presented between 1 and 2 records of causes of morbidity (Figure 3).

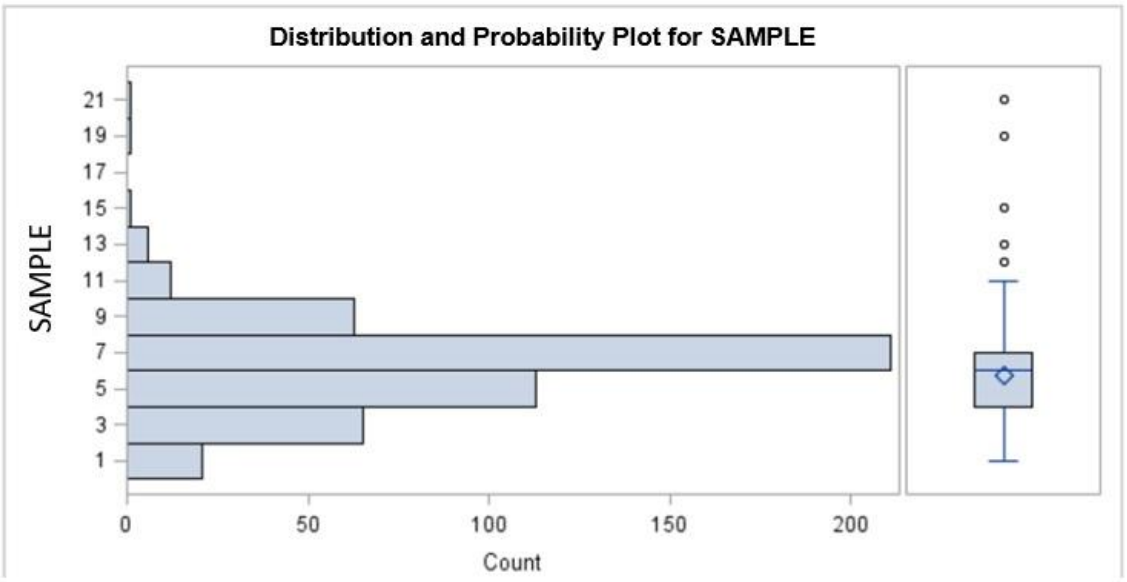

Fig. 3: Distribution and probability for records of causes of morbidities (N2).

The number of records of samples collected for histopathology (A1) was 2830 with an average of 5.72 ± 2.42 (C.V. 42.32%). The minimum value was 1, maximum value: 21, 1st Quartile (Q1): 4, Median: 6, 3rd quartile (Q3): 7, fashion: 6, asymmetry: 0.88, kurtosis: 4.74, defining a leptokurtic distribution curve. Most of the reports presented 7 histopathological samples recorded (Figure 4).

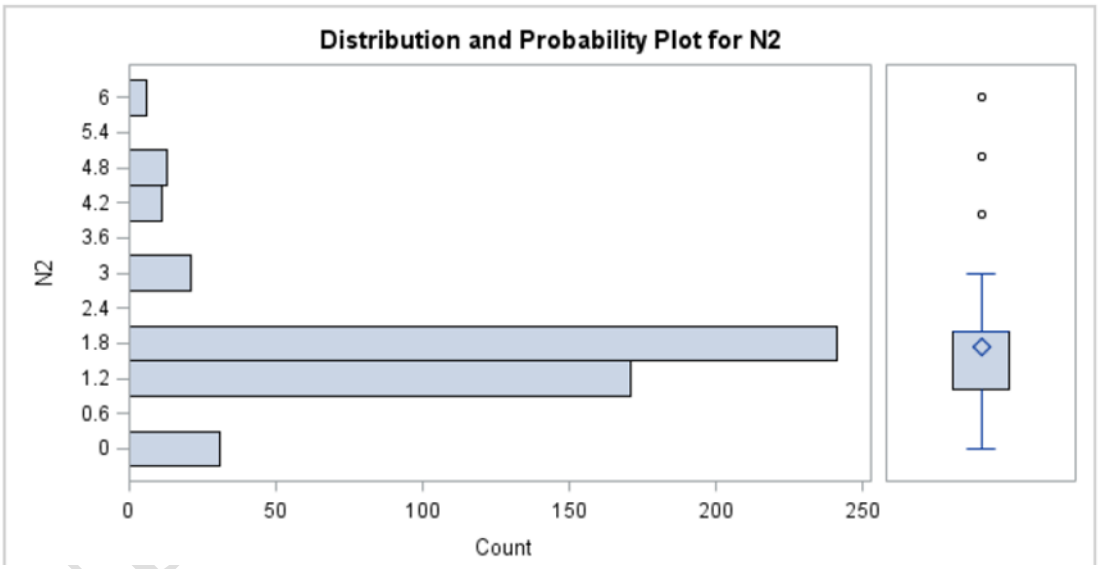

Fig. 4: Distribution and probability for collected sample records (A1).

A total of 103 autolysis (A2) records were found with a mean: 0.2 ± 0.5 (C.V. 251.46%). The minimum value was 0, maximum value: 4, 1st Quartile (Q1): 0, Median: 0, 3rd quartile (Q3): 0, fashion: 0, asymmetry: 3.07, kurtosis: 11.62, defining a leptokurtic distribution curve. Most reports did not present autolysis records (Figure 5).

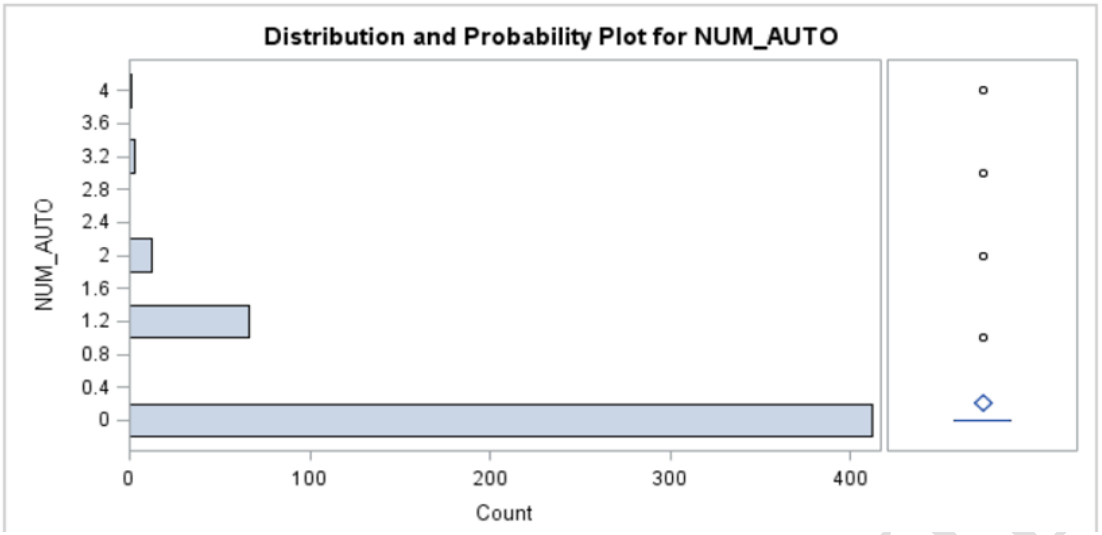

Fig. 5: Distribution and probability for autolysis (A2) records.

After the application of normality tests, it can be observed that the variables, focus of the present study, did not present normal distribution (Table 1), evidenced by the p-value $\leq \alpha$ (h0 is rejected), that is, it cannot be admitted that the data set in question have a normal distribution.

Table 1: Kolmogorov-Smirnov (KS) and Shapiro-Wilk (SW) normality test for mortality, morbidity, sample and autolysis.

Variables	Test	Statistic (α)	p-Value
Mortality (N1)	KS	D = 0,236062	<0.0100
	SW	W = 0,885785	<0.0001
Morbidity (N2)	KS	D = 0,299771	<0.0100
	SW	W = 0,785121	<0.0001
Sample	KS	D = 0,141709	<0.0100
	SW	W = 0,925977	<0.0001
Autolysis	KS	D = 0,488572	<0.0100
	SW	W = 0,447728	<0.0001

There was a moderate positive correlation (0.5-0.7) between A1 with N2 and between A1 with N1, significance < 0001 (Table 2).

Table 2: Pearson Coefficient Correlation Test for variables

Pearson Correlation Coefficients, N = 494				
Prob > |r| under H0: Rho = 0				
	N1	N2	Sample	NUM_AUTO
N1	1.00000	0.61358	0.55711	0.17083
		<.0001	<.0001	0.0001
N2	0.61358	1.00000	0.65976	0.16437
	<.0001		<.0001	0.0002
Sample	0.55711	0.65976	1.00000	0.35735
	<.0001	<.0001		<.0001
Number of autolysis	0.17083	0.16437	0.35735	1.00000
	0.0001	0.0002	<.0001	

The increase in the number of records for biological samples collected is related to an increase in the number of records for diagnoses of mortality and morbidity.

Between A1 and A2, there was a weak positive correlation (0.3-0.5) with significance < 0001. The increase in the number of records of biological samples collected is related to a minimal increase in the number of autolysis records.

The comparative analysis between the number of records of biological samples collected and the number of autolysis records showed that the presence of autolysis in the records of histopathological results has significance with P< 0001.

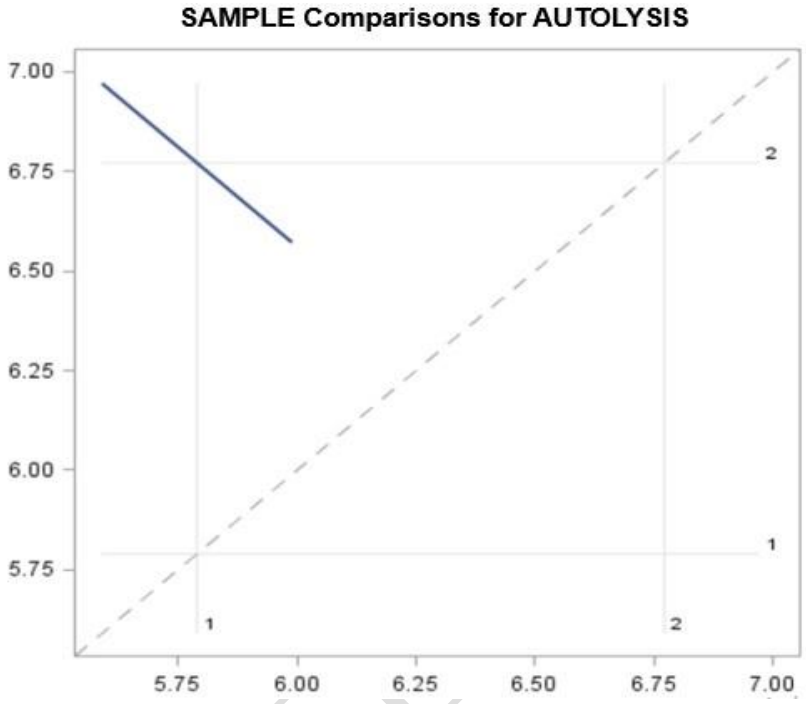

Fig. 6: Comparison between the numbers of records of biological samples collected (A1) and the number of autolysis records (A2).

The number of autolysis records also has significance P<0001 when compared to the number of records of causes of mortality and morbidity.

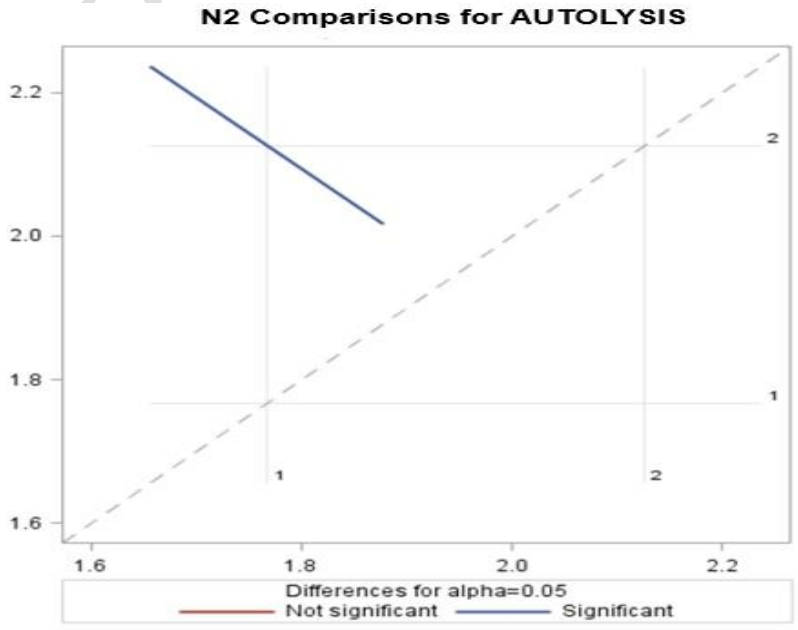

Fig. 7: Comparison between the number of records of causes of mortality (N1) and the number of autolysis records (A2).

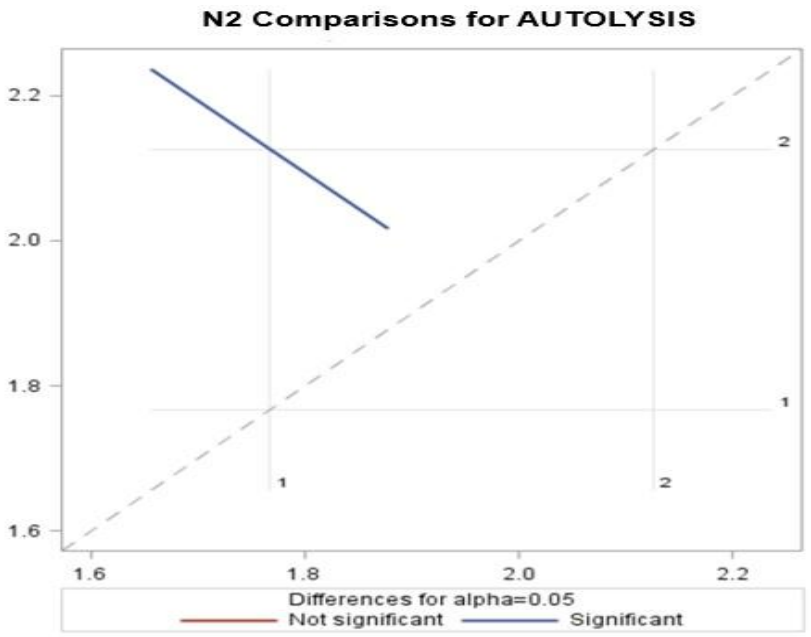

Fig. 8: Comparison between the number of records of causes of morbidity (N2) and the number of autolysis records (A2).

Figures 6, 7 and 8 shows respectively, that the comparison between the A2 with A1, N1, and N2 was significant so that the lower the number of autolysis the higher the efficacy of sample collection and the higher the generation of diagnoses directly and indirectly associated with death.

When comparing the number of records of biological samples collected with the number of records of causes of mortality and morbidity, it was evidenced that the collection of more than seven (7) biological samples in a necroscopic examination does not mean an increase in the number of records of causes of mortality and morbidity.

The results obtained through ANOVA (Table 3) generated a p-value of 0.0001 for the Wilcoxon test, represented by $p > |Z|$, this value less than the 5% adopted in this study ($\alpha = 0.05$). Using the Kruskal-Wallis test, significant results were obtained, since the chi-square p-value was <0.0001, similar to those observed for the Wilcoxon test. Both tests show the significant effect of the difference between the variables on the determination of autolysis.

Table 3: Analysis of variance of the effect between the variables used in this study, generated from the Wilcoxon and Kruskal-Wallis (KW) tests.

Variables	Test	Statistic (α)	p-Value
N1	KS	D = 0,236062	<0.0100
	SW	W = 0,885785	<0.0001
N2	KS	D = 0,299771	<0.0100
	SW	W = 0,785121	<0.0001
Sample	KS	D = 0,141709	<0.0100
	SW	W = 0,925977	<0.0001
Autolysis	KS	D = 0,488572	<0.0100
	SW	W = 0,447728	<0.0001

In addition to belonging to the National Network established by Ordinance No. 1,405 of July 29, 2006, the SVO-TO is part of the National Health Surveillance System, which can establish agreements with public institutions of Higher Education, philanthropic institutions, Secretariats of Public Security or equivalent for the operationalization of the SVO of the network[6].

The information produced in the VOS helps epidemiological control by prioritizing cases of poorly defined natural deaths due to infectious diseases of compulsory notification or unusual diseases[11,6,12,14]. It was observed the importance it minimizing the number of autolysis of the specimens collected during necroscopic examination in the SVO because they, directly and indirectly, interfere in histopathological diagnoses and morbidity and mortality.

During necropsy in the SVO-TO, macroscopic of cavities, organs, collection, and packaging of tissue samples that will be referred for histopathological examination in a laboratory of outsourced pathological anatomy is performed. In these processes, factors such as the time elapsed between death and necropsy, the type of basic disease that caused death, incorrect macroscopic analysis, extraction of already deteriorated tissue samples and poor fixation or non-fixation in formaldehyde may, among others, rise to autolysis.

There is a recommendation for cuts in standard blocks at the time of autopsy[15], however in the SVO -TO, at the discretion of the necropsies physician, segments, fragments or entire viscera can be collected to be fixed in 10% formaldehyde and sent to the laboratory Outsourced.

An adequate amount of fixator consists of at least 10 volumes of fixer for 1 volume of fabric. Contaminated fasteners should be replaced by fresh solution[16]. However, the morphology of the tissue sample collection and the way it was extracted and packaged before being sent to the laboratory may facilitate non-fixation and autolysis.

Considering the brain, for example, there is a recommendation that remains fixed for about 15 days before cutting, due to decreased tissue consistency[17]. Microwave energy in combination with formalin or alcohol fixation is techniques employed[18]. Electrochemical methods have also been researched for rapid fixations of brain tissues[19].

The vials in which the samples are packed in the SVO-TO are not standardized, nor the place where they are stored before sending to the outsourced laboratory. Added to the time between sample collection during necropsy and the time at which it is analyzed may contribute to autolysis. The quality of tissue can be compromised by increased exposure to air, as occurs in conventional autopsies. The cooling of the tissues, a method that reduces the rate of autolysis, was confirmed as superior to vacuum sealing, which used a cooling of 4 ºC[20].

The application of microwave energy accelerates fixation by aldehydes and alcohol fasteners, however, care should be taken regarding overheating that alters nucleus and cytoplasm, hindering microscopic interpretation. The solution lies in the cooling of the fabric by replacing the fastener heated with one at room temperature[21].

Excessive handling or intense rinsing of organs should be avoided, however, the slight rinse of tissues with water causes few deleterious effects on specimens[22].

Necropsies with higher amounts of tissue samples collected in the SVO -TO may be related to the occasional fetal deaths examined. In these cases, the Letulle technique used by necropsies physicians allows monoblock evisceration and 10% formaldehyde packaging. The absence of macroscopic changes in some necropsies may induce the necropsies physician to collect a greater amount of biological samples for diagnostic elucidation, but the present study does not allow this analysis.

Placing similar density fabrics together, in cassettes, facilitates cutting. In view of better labeling, many institutions are preferring printed cassettes with sequential numbers such as A1 and barcodes. When possible, samples of the organ parenchyma should follow aces of capsules, serous surfaces, mucosa or endothelium. To collect bone samples for decalcification, a hammer and bone knife are preferable to a bone saw. The latter leaves bone dust as artifact[16].

In the SVO - TO, the low amount of biological samples collected may be related to the technique chosen by the Necropsist physician. However, reducing the number of biological samples may reflect on the reduction of autolysis and morbidity diagnoses. As Pearson's correlation shows, the increase in the number of tissue samples collected (A1) increases the number of mortality (N1) and morbidity (N2) diagnoses.

According to Quintella (S/D), all organs should be collected, regardless of the presence of macroscopic anatomopathological alterations, and their samples sent for histopathological examination. According to Saukko; Knight15 (2004), forensic pathology should be collected at least the liver, spleen, kidney, heart, lung, thyroid, adrenal, pancreas, muscle and brain. However, the study showed that a higher collection of collected samples implies a greater amount of autolysis.

An ideal representation of all organs, according to the Autopsy Manual of the Brazilian Society of Pathology, involves the production of about 40 slides[23]. Pearson's weak positive correlation between the number of records on biological samples collected and a number of records on autolysis emphasizes the need to standardize the amount of tissue samples collection of autopsied organs.

The mismeasured removal of tissues may amount to the chances of tissue degradation. When comparing the number of records of biological samples collected with the number of records of causes of mortality and morbidity, it was evidenced that

the collection of more than seven (7) biological samples in a necroscopic examination does not mean an increase in the number of records of causes of mortality and morbidity.

The absence of standardization is one of the factors that can hide diagnostics under microscopy and establish a reasonable number of fragments per autopsy that will prevent excessive preparation of slides and therefore a burden on the health system[24]. Autolysis occurs with the extravasation of lysosomal enzymes, which destroy the cell's own components, causing the impairment of tissue architecture[25–27]. Unlike surgical tissue, the autopsy material undergoes postmortem autolysis, to a degree that depends on the time interval since death, body size, storage conditions and underlays of the disease[16].

Autolysis compromises microscopic diagnoses. When analyzing causes of discrepancies between macroscopic and microscopic diagnoses, IDALINO; GOMES; CURY[24] (2004) highlighted that, due to autolysis, diseases of the digestive tract pointed out by macroscopy are hardly confirmed to histopathology. McVie[28] (1970), when examining the detection of unrelated myocardial infarctions in postmortem tissues, found that the color with nitroblue tetrazolium of macroscopic sections of the myocardium was affected by autolysis since the color depends on enzymatic activity.

As for the minimum time for necropsy, there is no regulatory legislation for cases of natural death. Services such as the SVO - Care Complex of the Faculty of Medicine of Marília use an adaptation of the precepts of the Code of Criminal Procedure (CPP) - L003.689-1941, which in article 162 guides the performance of necropsy in IML, at least six hours after death, unless pathologists deliberate the anticipation of this time[30].

A feasibility study of tissue samples from necropsy presented by Van der Linden et.al[23] (2014) found that the reduction of the postmortem interval improves the quality of the samples. IN the SVO-TO the practice of waiting six hours after the time of death to perform necroscopic tests is the standard, or at the discretion of the necropsies physician on duty. The present study does not allow establishing the impact of this time pattern to perform necropsy with the presence of autolysis of the collected samples.

The need for the almost immediate release of the body for bereaved relatives after necropsy causes necrosis physicians of to issue OD only with the causes of deaths diagnosed by pathological anatomy (macroscopy associated with clinical reports), without the correlation with histopathological examinations. When comparing the pathological information described in OD with the information in the definitive autopsy report, which includes histopathology and other complementary tests, different diagnoses are often perceived[24].

The Royal College of Pathologists and the Council of Europe of 1999 recommend that histology be done on all autopsies[15]. Histopathological examination is fundamental to support macroscopic findings, especially for diseases in which macroscopic manifestations are precarious or absent. An example is an infectious process, the etiology of which is defined exclusively by histopathological study[23].

The limitation of this study is in the quantitative and non-qualitative exclusive analysis of the biological samples collected and the causes of morbidity mortality, preventing results on which types of samples suffer more or less autolysis and their impacts on the quality of diagnoses.

The lower number of autolysis implies higher possibilities of diagnosis of morbidity and mortality, suggesting a higher quality of these diagnoses. Standardizing the activities of collection, packaging, processing, and transport of biological samples in SVO-TO can reduce the presence of autolysis. The absence of autolysis is an indicator of the quality of tissue samples. The study showed that despite the existence of autolysis in the samples collected by the SVO-TO, the low number of autolysis indicates efficiency in the process of collecting, packaging and transporting service samples.

Considering that health indicators are formulated with the collaboration of vital statistics, it is assumed the importance of defining the causes of deaths by THE. Determining the impact of VOS on elucidating mortality diagnoses should be the subject of continuous study by the organs dealing with death surveillance[1].

4. Conclusion

The amount of tissue samples collected in SVO of the State of Tocantins/Brazil necropsies positively impacts the amount of autolysis. The number of mortality and morbidity diagnoses recorded in SVO reports increases the higher the number of samples

collected by necropsies physicians. However, collecting more than seven tissue samples in a single necropsy does not impact the amount of mortality and morbidity diagnoses, suggesting a bias of possibility of quantitative standardization of biological samples collected in necropsies carried out by the SVO of the State of Tocantins. This is an indicator that could reduce costs without prejudice the production of reliable vital statistics for the Mortality Information System.

ANNEX 1 - Research Ethics Committee by substantiated opinion number: 2.708,612

UNIRG UNIVERSITY

CONSUMPTION OPINION OF THE CEP

Researcher: ARTHUR ALVES BORGES DE CARVALHO

Search Title: Analysis of biological samples collected for histopathology exams

Proponent Institution: UNIRG Foundation / UNIRG University

Version: 190514718.3.0000.5518

CAAE:

Thematic Area:

RESEARCH PROJECT DATA

Opinion Number: 2,708,612

OPINION DATA

Cross-sectional observational analytical study, performed on autopsy reports already completed by necropsist doctors from SVO-Palmas-TO, who have already been handed over to bereaved relatives and dealing with surveillance of state and municipal deaths.

Project presentation:

GENERAL

- Analyze the quantity and quality of biological samples recorded in necroscopic reports of the SVO of the State of Tocantins, 2012-2016

SPECIFIC

- Identify the quantity of biological samples recorded in necroscopic reports in the State SVO from Tocantins;

-Identify the quality of the biological samples recorded in the necroscopic reports in the SVO of Tocantins;

- To elaborate the relation between the quantity and quality of biological samples with the number of causes of mortality and morbidity recorded in necroscopic medical reports in the SVO of the state of Tocantins.

The authors evaluate the risks and benefits. The risks that permeate this study include the possible exposure of the elements that addict the medical practice of improper collection of biological samples, inadequate production of information from mortality, as well as the inherent risks of exposing the causes of death of patients undergoing necropsy within the Tocantins State SVO. However, they will be minimized as they will not be exposed under any hypothesis, data that allow the identification of the patient and / or family members, compliance with the ethical precepts of Resolution 466/2012/CNS.

The expected benefits of the study permeate the production of homogeneous sampling within the SVO that directly or indirectly provides an improvement in the diagnosis of causes mortality and morbidity, improving vital information and statistics in the Mortality.

Risk and Benefit Assessment: Project has scientific relevance, is well written, clear and objective.

Research Comments and Considerations: All documents are in accordance with resolution 466/2012.

Compulsory Terms Considerations: Do not have.

Recommendations: The project follows the norms of resolution 466 and does not present ethical violations regarding the requirements. Therefore, the project is approved by this committee for its execution.

Conclusions or Pending Issues and List of Inadequacies: Dear authors, the points and questions pointed out in the reporting process were described sufficiently discussed and voted by the members of this committee. The project follows the norms of resolution 466, so it is approved for its execution.

Opinion Status: Approved

Needs CONEP Appraisal: No

Signed by

Wataro Nelson Ogawa

(Coordinator CEP/UnirG)

REFERENCES

1. Jorge MHPM, Laurenti R, Gotlieb SLD. Analysis of the quality of Brazilian vital statistics: the experience of implementation of SIM and SINASC. Ciência & Saúde Coletiva, v. 12, p. 643-654, 2007.

2. BRAZIL. Ministério da Saúde. Datasus. Accessed 01 november 2018. Available: <http://datasus.saude.gov.br/sistemas-e-aplicativos/eventos-v/sim-sistema-de informacoes-de-mortalidade>.

3. Azevedo, BAS et al. Evaluation of the implementation of death verification services in Pernambuco, 2012: estudo de casos múltiplos. Epidemiologia e Serviços de Saúde, v. 25, p. 595-606, 2016.

4. Frias PG, Szwarcwald CL, Lira PI. Evaluation of information systems on live births and mortality in Brazil in the 2000s. Cad Saude Publica. 2014 Oct;30(10):2068-80

5. Figueiroa BQ, Vanderlei LCM, Frias PG, Carvalho PI, Szwarcwald CL. Analysis of the coverage of the Mortality Information System in Olinda, Pernambuco, Brasil. Cad Saúde Pública. 2013 mar;29(3):475-84.

6. BRASIL. MINISTÉRIO DA SAÚDE. Ordinance No. 1,405 of June 29, 2006. Establishes the National Network of Death Verification and Clarification Services of The Cause Mortis
(SVO). Diário Oficial da República Federativa do Brasil, 2006.

7. Carvalho AAB. Study on the records of the death verification service in the mortality information system for the state of Tocantins, 2010-2012. Tese de Doutorado. Universidade de São Paulo, 2016.

8. BRASIL, RESOLUÇÃO – CIB Nº 003 /2007, of February 28, 2007. It provides for the draft ordinance establishing the Death Verification and Death Cause Clarification Service (SVO); Diário oficial da União. Palmas; 4 de abril de 2007, p. 33

9'. SUPERINTENDÊNCIA DE VIGILÂNCIA, PROTEÇÃO E PROMOÇÃO À SAÚDE - SVPPS/SVO. Protocol for the activation of the Tocantins State Death Verification Service for cases of ill-defined natural deaths of epidemiological interest. [online]. Accessed 07 de March 2018. Available:<https://central3.to.gov.br/arquivo/254474/>.

10. CENTERS FOR DISEASE CONTROL AND PREVENTION. Report of the panel to evaluate the US standard certificates. Hyattsville, MD: Division of Vital Statistics, National Center for Health Statistics; 2001. <http://www. cdc.gov/nchs/data/dvs/panelreport_acc.pdf>.

11. MATHERS CD. et al. Counting the dead and what they died from: an assessment of the global status of cause of death data. Bulletin of the world health organization, v. 83, p. 171-177c, 2005.

12. BRASIL. MINISTÉRIO DA SAÚDE. SECRETARIA DE VIGILÂNCIA EM SAÚDE. Ordinance No. 116, of February 11, 2009. Regulates data collection, flow and periodicity of sending information on deaths and live births to Health Information Systems under the management of the Health Surveillance Secretariat. Diário Oficial da União, 2009 a.

13. BRASIL. MINISTÉRIO DA SAÚDE. Manual for investigation of death with ill-defined cause, 2009b.

14. BRASIL. MINISTÉRIO DA SAÚDE. Health Surveillance Secretariat. Department of Health Situation Analysis. Instruction Manual for Completing the Death Certificate. Brasília: Ministério da Saúde. Fundação Nacional de saúde, 4.ed.p.55, 2011

15. Saukko P, Knight B. The forensic autopsy. Knight's forensic pathology. 3rd ed. London: Edward Arnold, p. 28-47, 2004.

16. Connolly AJ, Finkbeiner WE, Ursell PC, Davis RL (2016) Autopsy Pathology: A Manual and Atlas. 3nd edition. ISBN: 9780323295369 pg. 90.

17. POWERS JM. Practice guidelines for autopsy pathology. Autopsy procedures for the brain, spinal cord, and neuromuscular system. Autopsy Committee of the College of American Pathologists. Archives of pathology & laboratory medicine, v. 119, n. 9, p. 777-783, 1995.

18. Kok LP, Boon ME. Microwaves for microscopy. Journal of microscopy, v. 158, n. 3, p. 291-322, 1990.

19. Garzon-de la Mora, P. La Mora et al. Electrochemical fixation techniques. I. Electrochemical fixation of the human brain. Archives of medical research, v. 27, n. 1, p. 37-42, 1996.

20. Kristensen Thomas et al. Vacuum sealing and cooling as methods to preserve surgical specimens. Applied Immunohistochemistry & Molecular Morphology, v. 19, n. 5, p. 460-469, 2011.

21. Suvarna SK, Layton, C. Bancroft's theory and practice of histological techniques, 7th edition. Churchill Livingstone Elsevier. Philadelphia, PA, USA, 2012.

22. Cotton DWK, Stephenson TJ. Impairment of Autopsy Histology by Organ Washing Myth. Medicine, Science and the Law, v. 28, n. 4, p. 319-323, 1988.

23. Echenique LS et al. Correlation between macro and microscopic findings in 200 consecutive autopsies: analysis of the cost/benefit value of the complete histopathological study of autopsies. Jornal Brasileiro de Patologia e Medicina Laboratorial, 2002.

24. Idalino CV, Gomes EE, Cury PM. Comparative study of macro and microscopic diagnoses of autopsies: analysis of difficulties and possible causes of error. J. Bras. Patol. Med. Lab. Rio de Janeiro, v. 40, n. 5, p. 325-331. Oct. 2004.

25. Coe JI. Postmortem chemistry update, emphasis on forensic application. Am J For Med Pathol 1993; 14: 91-117.

26. Kumar V et al. Basic pathology.7th ed. Saunders, Philadelphia, 2003

27. Tomita Y. et al. Ultrastructural changes during in situ early postmortem autolysis in kidney, pancreas, liver, heart and skeletal muscle of rats. Legal medicine, v. 6, n. 1, p. 25-31, 2004.

28. McVie JG. Postmortem detection of inapparent myocardial infarction. Journal of clinical pathology, v. 23, n. 3, p. 203-209, 1970.

29. Van Der Linden A, Blokker BM, Kap M, Weustink AC, Robertus JL, Riegman PHJ, Oosterhuis JW. Post-mortem tissue biopsies obtained at minimally invasive autopsy: an RNA-quality analysis. PLoS One; 9(12): e115675, 2014.

30. ELLINGER, F.; BEZERRA, K.C.A. Manual of Procedures of the Death Verification Service of Marília. Famema, p. 15, 2011.