International Journal of Nursing and Health Care Research

OPEN ACCESS

Petronela Coblișan A, et al. Int J Nurs Health Care Res 6: 1460

www.doi.org/10.29011/2688-9501.101460

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Research Article

Biological Sampling for the Diagnosis of SARS-CoV-2 Infection

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Citation: Petronela Coblișan A, Pop CF, Valentina TS, Borcău AG, Cherecheș-Panța P (2023) Biological Sampling for the Diagnosis of SARS-CoV-2 Infection. Int J Nurs Health Care Res 6: 1460. DOI: 10.29011/2688-9501.101460

Received Date: 15 August, 2023; **Accepted Date:** 22 August, 2023; **Published Date:** 24 August, 2023

Introduction

The infection with the new SARS-Cov2 led to a new pandemic, the entire world map being affected by the health crisis generated by this pandemic. The medical world was and is under pressure to quickly and correctly diagnose patients with COVID-19, to treat them effectively, to limit epidemiological outbreaks and to increase the population's awareness of vaccination.

The rapid and correct diagnosis of people infected with SARS-Cov2 first of all requires a correct technique for collecting biological samples, taking into account the increased probability of 30% to obtain false negative test results in the case of symptomatic patients, due to collection errors [1].

For this reason, we applied a questionnaire among the medical staff of the Cluj-Napoca Children's Emergency Clinical Hospital, in order to evaluate their perception regarding the nasopharyngeal secretion collection technique, in relation to the clinic's protocol, but also their perception regarding the discomfort felt during the test.

Also, the rapid and correct detection of patients requires rapid antigenic tests with rapid diagnostic performances. Consequently, we wanted to study the diagnostic performance of the rapid antigenic tests used in the Pediatric Clinic 3 for testing patients hospitalized in the clinic.

Design and Methods

Study Design

This is an observational and descriptive study. The data collection was cross-cutting in the first part and retrospective in the second part. The samples were of a representative type.

The present study had two parts:

The first part addressed the medical and auxiliary staff in the Pediatric Emergency Hospital for Children in Cluj-Napoca. They voluntarily replied to the questionnaire "Taking biological samples from medical staff for diagnosis of SARS-CoV-2 infection", drafted in Microsoft Word and Google forms, and distributed both in the physical and online form via social media platforms (WhatsApp and Facebook) to those willing to participate in this study.

A total of 88 people in the answered the questionnaire, between June 1st and July 1st, 2021 [2].

For the second part, we looked at the observation sheets of patients admitted to the Pediatric Hospital between February 1st and June 30th, 2021, who were tested for COVID 19 infection both by RT-PCR and rapid antigenic testing.

Presentation of the operation

For the first part of the study, the questionnaire was elaborated based on literature recommendations and hospital protocol. In

the questionnaire header, it was specified that the data collected is anonymous and will be processed and used in this work. By completing the questionnaire, the participants agreed to participate in this study.

The questionnaire had 19 questions, all of them mandatory, structured in 2 parts: The first part included 7 questions about the personal data of the participants: age, sex, graduated school, function in the hospital, years of experience, hospital in which they operate, and hospital where the biological sample was collected for testing for infection with SAR-Cov2. The questions were both open-ended and multiple-choice.

The second part of the questionnaire included 12 questions, 10 assessed the sampling technique and 2 of them reflected the discomfort caused by the sampling technique.

The questions had multiple answers, with participants having to choose between YES, NO, I DO NOT KNOW, THAT WAS NOT THE CASE.

For the second part, participants in the study were included in the study according to the following inclusion criteria:

- age: 0 to 18 years
- Admission to the 3rd Pediatric Clinic between February 1st and June 30th, 2021;
- Patients who presented in the observation sheet the results of an RT-PCR test and rapid antigen test for diagnosis of infection with SAR-CoV-2.

Exclusion criteria:

- Being admitted to the clinic within a different time frame;
- Patients who presented the result of only one of the tests.

The inclusion criteria was met by 133 patients. They were tested using the RT-PCR method and the fast antigen test from the DDS Diagnosis (Romania).

Statistical analysis

Descriptive statistical methods have been used to sum up the replies to the questionnaire +and those related to patients participating in the second part of the Dissertation Paper.

As regards the questionnaire, following the collection of the replies, we achieved a correctness score of the nasal secretion collection technique based on the 10 items in section 2 of the sampling technique questionnaire. The YES answer to questions 1-10 and the answer was not the case in question 4 were rated by 1; i do not know by 0.5 and not by 0. The points obtained in each question were summarized, obtaining scores from 0 to 10, with 10 being the maximum score obtained when all steps were followed in the sampling for COVID testing. We considered a very low score between 5 and 6, low between 6 and 7, average between 7 and 8, high between 8 and 9, and very high between 9 and 10 [3].

Databases and data analysis were processed using Microsoft Excel. For the testing of the association between qualitative variables, we used the CI-square and Pearson Correlation test for dichotomy variables as well as for the comparison of scores between groups in the t-Student test.

We considered the results to be statistically significant if $p<0.05$.

Results

The first part of the work carried out on the basis of the questionnaire

This study was attended by employees from all 3 clinics of the Emergency Hospital for Children in Cluj-Napoca. The higher number of participants, 38.6%, were from the 3rd Pediatric Clinic. 34% of participants work at 2nd Pediatric Clinic, while 27.2% in the 1st Pediatric Clinic. The testing was carried out in the clinic in which they operate.

Of the 88 participants, 43.1% graduated the Faculty of Medicine and worked as a resident, specialist, or primary doctor at the Emergency Hospital for Children. Their average experience in the field over the years was 6.2 years.

32.9% of the participants were nurses in the hospital with 12.8 years of experience in the field; 37.9% of nurses are graduates from the Medical Assisting Faculty and 62% are post-secondary Medical Assisting graduates.

23.8% of those who replied to the questionnaire did not have completed university or medical studies. Their experience in this field is 12.2 years.

Replies of the participants to section II of the questionnaire

The answers of the participants to the sampling questions are given in the following Table 1.

	Question	Answer		
		Yes (%)	No (%)	Don't know OR Was not the case (%)
1	Was the position during harvesting with the head slightly bent back?	78	22	-
2	Lifting the tip of the nose?	52	42	6
3	Was the assistant positioned on the side of the nostril where the collection was performed?	59	37	4
4	Has the functional nostril been established?	40	55	6
5	Was the hygiene of the nasal cavity performed before the test?	21	4	75
6	Was the nasal swab inserted up to the level of the posterior wall?	93	2	5
7	Was the pad rotated for 10 seconds?	77	11	12
8	Was the tampon withdrawn slowly without touching the skin?	86	9	5
9	Did you wear the mask during the test?	61	37	2
10	Was the result communicated within 15 minutes?	97	1	2
11	Pain	47	53	-
12	Sneezed or coughed	45	55	-
13	Pain and sneezed	20	80	-

Table 1: The answers of the participants to the sampling questions.

Looking at the participants' responses, 78.4% said that the position during the test was with the head slightly bent to the back, supported on the chair and towards the nurse, and in 52% of cases the nose tip was raised for the correct insertion of the stick.

59% of those surveyed said the assistant was positioned on the side of the nostril where the nasal secretion was collected. In 55% of cases, it was not determined which one is the functional nostril. In 73% of cases, the tested patient had no nasal secretions required to wash the nasal cavity. For those with nasal secretions, most were invited to blow their nose prior to testing. The nasal swab was introduced to the posterior wall of the nasopharynx in 93% of cases, rotated and held in place for 10 seconds at 77%, and was removed slowly and without reaching the skin at 86.3% of the participants [4-6].

During collection, only 61.36% of the participants wore the buccal cavity protection mask. The result of the rapid test was correctly communicated at 15 minutes in 86% of cases.

Regarding the discomfort experienced during testing, 46.5% of participants claimed that they felt pain during testing, and 45% sneezed or coughed during and immediately after collection. Only 20.4% felt in the same time and pain and sneezed or coughed during harvesting.

The average correctness score of the nasal secretion collection obtained was 7.6 (10.2%): 9 (22.7%) for very low value responses, 20 (22,7%) for low value responses, 14 (15,9%) for medium value, 20 (%) for high value responses, and 25 (28,4%) for very good value.

In order to analyze the differences between scores according to the completed studies, we have applied the ANOVA comparison test of distributions. We observed that there are no significant statistical differences between the correctness scores obtained in the 3 categories with the average scores being found ($p=0.44$).

We have also analyzed the average score obtained by nurses with university and postlyceal school.

There are no significant statistical differences between the responses generated by the 2 nurse classes [7].

We wanted to analyze whether the correctness scores calculated based on the answers of the study participants differ depending on the clinic in which they are working. The averages of the scores obtained according to the clinic of provenance of the participants. $p = 0.49 > 0.05$, which led to the conclusion that there are no statistically significant differences between the scores obtained depending on the clinic where the samples were collected.

Initially, we wanted to see if there was an association between the sex of the participants and the pain reported during the test, but $p = 0.65$. Thus, we found that there is no statistically significant association between sex and reported pain. Similarly, we checked for cough and sneezing symptoms during and after testing. In the Chi square test we obtained a $p = 0.07$, which is why we concluded that there is no statistically significant significance between those parameters.

Next, we applied the Chi square test to see if there was an association between participants' office (doctor, nurse, and other functions) and pain reported during testing, $p = 0.001$. Thus, I was able to demonstrate that there is an association between function and the painful threshold.

Similarly, we applied the same test to verify the association between the function participants and symptoms reported after testing like sneeze or cough, the conclusion being that there is no statistically significant association between the 2 variables [8].

To check the association between the correct position of the head (bent on the back) during the test and the pain felt, $p = 0.65$. Thus, we demonstrated that there is no statistically significant association between head position and pain experienced during nasal swab collection. We also verified the existence of a correlation between the 2 variables by applying the Pearson correlation test for dichotomous variables. We obtained a coefficient $r = 0.003$ and a $p = 0.97$. Thus the correlation between the two parameters is weak and statistically insignificant [9].

That the nurse's position on the side of the nostril influences the pain felt by the patients, $p = 0.48$. This value is greater than 0.05 and does not allow us to state that between the pain and the position of the assistant is an association. We verified the existence of the correlation by applying the Pearson correlation test and we obtained $r = -0.13$ and $p = 0.22$.

In the next step I wanted to establish an association between the step of respecting the functional nostril and the pain felt. The correlation test applied in this case led to an $r = 1$ and $p = 0.0001$. We concluded that the establishment of functional nostrils positively influences the onset of pain.

To test the hypothesis that lifting the tip of the nose influences the pain felt during the test, we created contingency table 11 and applied the Chi square test. The p-value obtained was 0.29, unsatisfactory for the demonstration of association. And in this case we applied the Pearson correlation test and obtained $r = -0.08$ and $p = 0.45$ [10-14].

Part two of the study

For part 2 of the study, 133 patients were included. Socio-demographic parameters are shown in Table 2.

Parameter	
Average age (years)	2,3
Sex (F/M)	65/68
Background (U/R)	63/70

Table 2: Description of socio-demographic parameters.

Of the 133 patients, 25 were hospitalized in February, 20 in March, 17 in April, 37 in May and 34 in June.

The reasons for admitting them are shown in Table 3 and the primarly diagnostics on discharge are shown in Table 4.

Reasons for presenting	**Percentage (%)**
Fever	67,6%
Cough	39.8%
Rhinorrhea	24,9%
Dyspnea	15,7%
Digestive symptoms	24,9%
Others symptoms	30,8%

Table 3: Reasons for presenting patients in Pediatric 3.

Diagnosis at discharge	**Percentage (%)**
Nonspecific febrile syndrome	13,6
Acute upper respiratory tract infections	62,4
Acute lower respiratory tract infections	38.3
SARS-COV-2 infection	3,8
Acute gastroenteritis	8,3
Urinary tract infections	8,3

Table 4: Diagnosis at discharge.

Rapid antigen test performance

In order to calculate the sensitivity and specificity of the rapid antigenic test. However, I was able to observe that out of the 133 hospitalized patients, only 5 had a positive RT-PCR test, previously tested negative with the rapid antigenic test. Based on these values we calculated a negative predictive value, which coincides with the accuracy of the test of 96.2%.

Conclusions

1. The study involved 88 employees of the Cluj-Napoca Children's Emergency Clinical Hospital, most of them female.
2. Pediatric clinics employ more graduate nurses from the Post-secondary School than from the Faculty of Medicine.
3. The least respected step is to determine the functional nostril.
4. Pain, sneezing, and coughing during testing were reported by both male and female participants.
5. The accuracy of the rapid antigenic test used in the Emergency Clinical Hospital for Children is 96.4%.

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