Effectiveness of ophtascan 2 diabetes screening in Lubumbashi: Pilot study on screening for cancer and type

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ABSTRACT: Introduction: Screening and early treatment are the best strategy for controlling cancer and type 2 diabetes (T2DM). Based on artificial intelligence, new software Ophtascan allows the early detection of the following cancers: cervix, endometrium, breast, prostate, lung as well as type 2 diabetes, from the image of the eyes. The objectives of this study were to test the reliability of the test in the detection of type 2 diabetes and to present the prevalence of oncological pathologies detected.

Methodology: screening was carried out in two stages: a technical test of the program and mass screening at the University Clinics of Lubumbashi and the Sendwe Hospital of Lubumbashi among volunteers from April 2023 to July 2023.

Results: Of the 98 volunteers screened including 32 men and 66 women, the risk of the following cancers was detected by Ophtascan: in men, 12.5%, 28% and 6% respectively for the prostate, lung (pre-cancer) and lung while in women we had 1.5%, 6%, 3%, 4.5% and 3% respectively for cervix (pre-cancer), cervical cancer, endometrial, breast (pre-cancer) and breast. This cancer screening trial was not accompanied by clinical confirmation of detected diseases due high cost and practical problems. T2DM trial was accompanied by lab blood test for confirmation of results. Proved sensitiviy of Ophtascan for T2DM achieved 91% within blind clinical trial and 100% within technical trial, and 72% of screened people did not suspect they had this disease, detected by Ophtascan.

Conclusion and recommendation: Ophtascan is feasible in our environment and seems to have high reliability for the detection of type 2 diabetes as screening tool. Ophtascan certainly detected most of the targeted cancers, but the low number of cases does not allow solid conclusions to be drawn. The difficulty of validation for all types of cancer mentioned above due to its high cost for patients, we propose to carry out a new pilot research project which will focus on cervical cancer, for which early treatment is possible at a low cost in our environment.

KEYWORDS: Effectiveness, ophtascan, screening, cancer, type 2 diabetes.

1 INTRODUCTION

According to WHO data (2016), the problem of cancer and diabetes in the DRC is not acute: they contribute to mortality of 3% and 1%, respectively [1]. But as indicated by [2], most of these statistics are collected especially in Kinshasa in private hospitals. The vast majority of the country's population is undiagnosed for these diseases because they cannot afford the diagnostics [2].

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Regarding the prevalence of diabetes in the DRC, the official figure is 4.8% [2], of which 92% is type 2 diabetes [3]. The rate of glycemic control in diabetic patients is extremely low, with local studies finding that control was not achieved in 68% to 86% of patients [2]. But even diagnosed diabetics are only diagnosed in the capital, Kinshasa, and much of the country is not diagnosed because of the high cost [2]. Undiagnosed diabetes represented 58.8% in the DRC. With this in mind, more than 75% of African countries do not have epidemiological data on the prevalence of diabetes in adults, and most of the available data often concerns urban settings. In the Democratic Republic of Congo (DRC), no nationwide study has been conducted on the prevalence of diabetes. Prevalence in urban areas of the DRC ranged from 11.7 to 15.5% in 2006, while in rural and semi-rural areas a much lower prevalence was reported, varying between 1.7% in 2006. 'East and 4.8% in the West from 2007 to 2015 [4].

Many doctors in the DRC do not take diabetes seriously. But, in fact, the consequences of diabetes are very tragic: diabetes is a major cause of blindness, kidney failure, heart attacks, stroke, lower limb amputation and early death [5].

"Cancer is a major public health problem in our country," said Pacifique Misingi Aye, director of the National Blood Transfusion Center in Kinshasa. "We must prioritize prevention and early detection to minimize the need for care at later stages in the poorest populations who are most affected. » [6]

Taking a closer look at even WHO statistics, only 1 in 10 women were diagnosed with cervical cancer in 5 years, and this is the type of cancer that women in the DRC suffer from the most and die [6].

Modern doctors know that mass screening makes it possible to detect diseases in the population at an early stage and send to expensive functional diagnostics only those people who need real treatment. Unfortunately, many screening tools are inaccessible to the majority of the DRC population, both in terms of price and accessibility to transport, so the problem of introducing a cheap mass screening tool and affordable in the DRC is very acute.

1.1 BRIEF INFORMATION ABOUT OPHTASCAN

The new computer program Ophtascan from the Swedish company Oncotech is an innovative screening tool that allows online screening for the risks of 5 types of cancer (cervical cancer, endometrial cancer, breast cancer, breast cancer, Prostate and lung cancer) and type 2 diabetes from eye photos. It allows for a few minutes to obtain the risk very cheaply for the person on the above diseases. The current version of the program is designed for use in public and private hospitals and clinics. It is based on proven clinical data from thousands of Russian patients and has CE marking. Photography can be done on modern model smartphones.

1.2 INFORMATION ON PILOT RESEARCH

In connection with the situation of screening and diagnosis in general in the DRC, we carried out a pilot research project at the University Clinics of Lubumbashi and at the Sendwe Provincial General Reference Hospital to test the reliability of the new innovative screening tool - the ophthalmological medical program from the Swedish company Oncotech "Ophtascan".

1.3 THE OBJECTIVE OF THE STUDY

1.3.1 GENERAL

contribute to improving the management of type 2 diabetes and the above-mentioned cancers through their detection and early treatment.

1.3.2 SPECIFIC

Test the reliability of the Ophtascan test in the detection of type 2 diabetes;

To test the reliability of the Ophtascan test in the detection of precancerous and cancerous lesions of the cervix, endometrium, breast, prostate and lung.

2   METHODOLOGY

2.1   RESEARCH DESIGN

This research was a multi-clinical validation study of diagnostic accuracy to assess the validity and reliability of the Ophtascan™ application to improve type 2 diabetes and cancer screening in Democratic Republic of Congo.

This research was a part of the multi-national study on the effectiveness of the Ophtascan™ application in Democratic Republic of Congo and eventually in Africa, such Ophtascan™ study will be carried out in South Africa, Kenya and Namibia.

Study consisted of 2 parts:

Part 1. Brief validation of screening tool Ophtascan™ to confirm its sensitivity and specificity for type 2 diabetes patients.

Part 2. Mass blind type 2 diabetes screening by Ophtascan™ with further comparison of Ophtascan™ and clinical diagnosis to validate accuracy of Ophtascan™ for type 2 diabetes. Also, the same people were screened for 5 types of cancer without further validation, just for to see and know how Ophtascan™ operates with cancer screening.

2.2   TARGET POPULATION

Part 1 study target population included 8 patients with a confirmed diagnosis of 2 type diabetes. Research team recruited the type 2 diabetes patients of University Clinics of Lubumbashi and the Sendwe Hospital of Lubumbashi and 6 healthy young volunteers-students of Lubumbashi University, 18-20 years old, with a clinically confirmed absence of diseases and no family background of type 2 diabetes.

Part 2 study target population included 98 volunteers - random selected people, various age and gender, without any diagnosis.

2.3   SAMPLING TECHNIQUES

Sampling technique in Part 1 was simple random sampling within patients University Clinics of Lubumbashi and the Sendwe Hospital of Lubumbashi with type 2 diabetes diagnosis.

Sampling technique in Part 2 was simple random sampling with patients of any diagnosis of University Clinics of Lubumbashi and the Sendwe Hospital of Lubumbashi.

2.4   DATA COLLECTION PROCEDURE

Patients' data was extracted from the hospital medical records information system. These real-world hospital-based health data are collected during routine healthcare.

- Sociodemographic data: age, sex, marital status, residence (district, region, urban/rural), ethnicity, educational level (tertiary, secondary, primary, none), occupation (retired/pensioner, unemployed, unskilled work, skilled work, professional), health insurance (public, private, public and private, none, other)

- Clinical data: diagnosis, clinical staging of disease, duration (in years) from the first encounter to a hospital to the final diagnosis, duration (in years) of disease from the initial symptoms and signs, laboratory and imaging tests, treatment, current signs and symptoms. Patients' clinical diagnosis was classified according to the International Classification of Diseases (ICD)

In addition, research team conducted interviews with study participants using a structured questionnaire in order to collect the study-specific sociodemographic and clinical data that complement the retrospective hospital-based routine healthcare data. This interview was conducted before taking photographs of the participant's eye iris.

2.5   DATA COLLECTION TOOLS

Through a prospective data collection process, research team collected sociodemographic and clinical data using standardized electronic data collection tools using the Open Data Kit (ODK).

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2.6   ANALYSIS

All tests were analyzed using SPSS statistical software.

The investigators evaluated the performance of the Ophtascan™ in the real-time detection of cancer and type 2 diabetes using the diagnostic accuracy, sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV). We compared the difference in PPV and NPV between the APP and real-world medical diagnosis.

3   RESULTS

Total number of volunteers screened: 98

Number of women: 66

Number of men: 32

3.1   TECHNICAL TESTS

14 volunteers screened including 6 healthy and 8 confirmed type 2 diabetics

The following results were obtained:

All 6 healthy people were detected healthy for type 2 diabetes by the test = 100% specificity;

The 8 cases of type 2 diabetes detected positive by Ophtascan=100% sensitivity

3.2   MASS SCREENING

The following results were obtained:

For cancer:

Among the 84 volunteers screened, including 24 men and 64 women, the risks were as follows:

Table 1.   Type of cancer risks detected by ophtascan on women

Type of cancer	Number of cases	Percentage
Cervical precancerous lesions	1	1,5%
Cervical cancer	4	6%
Endometrial cancer	2	3%
Breast precancerous lesions	3	5,7%
Breast cancer	2	3%
Total	12/64	18%

Table 2.   Type of cancer risks detected by ophtascan on men

Type of cancer	Number of cases	Percentage
Prostate precancerous lesions	0	0%
Prostate cancer	4	16,6%
Lung precancerous lesions	9	37,5%
Lung cancer	2	8,3%
Total	15/24	62,5%

For type 2 diabetes:

13 people were detected at risk of type 2 diabetes, or 15%

Among these:

11 confirmed cases and 2 unconfirmed cases;

9 out of 11 cases did not know they were diabetic, or 72%.

4   DISCUSSION

4.1   TYPE 2 DIABETES

Technical tests and mass screening detected 21 cases of type 2 diabetes, including 19 cases confirmed by Hb A 1C (HbA1c test ≥6.5%: sensitivity of 25% and specificity of 93%), or 90%. This specificity rate found is lower than that found in a study which was 93% [7]. This is explained by the fact that, for economic reasons and unavailability, 2 cases detected were not confirmed.

Oncotech claims a specificity of 96% and a sensitivity of 95% for the detection of type 2 diabetes. However, these results from technical and clinical trials in Russia have not yet been published.

72% of cases of type 2 diabetes detected by Ophtascan during screening were not aware of their disease; this finding is very important because it allows early treatment.

4.2   ONCOLOGICAL SCREENING

Despite the reduced number of cases, the risks of cervical cancer and breast cancer remain the most common oncological pathologies in women in our country as in many low- and middle-income countries [8] - In our study, we notes a slight predominance of risks of the cervix compared to those of the breast of around 6% to 5.7% of cases respectively. A study carried out at the University Clinics of Kinshasa and the General Reference Hospital of Kinshasa shows that cervical and breast cancers are the most prevalent in women with respectively 27.7% and 13.7% while in women The most predominant cancers in men are that of the lymphoid organs and the prostate (14%) [9]. In our study, we had a prevalence of 16.6% for the risk of prostate cancer. Prostate cancer is the most common cancer in men over 50 in Western countries. In Africa, the low level of medicalization and the difficulties in accessing health services make this condition less known and the diagnosis late, sometimes even undiagnosed [10]. We can see that almost all the cancers targeted by the OPHTASCAN program have been detected already at the precancerous stage; which corresponds to the discoveries of Professor Gantsev, a renowned Russian oncologist [11] on "cancer without tumor". The idea of using Ophtascan MC is based on the principle of screening, that is to say the detection of cancer in the early stages or precancerous conditions in people who are not registered as cancer patients: they have never been diagnosed and have not been treated for cancer.

5   CONCLUSION, RECOMMENDATIONS AND PERSPECTIVES

5.1   TYPE 2 DIABETES

The reliability of the test in detecting type 2 diabetes appears to be established. A project for mass screening on a larger scale of around 3000-5000 volunteers on the basis of which a report and recommendations to the National Ministry of Health, Hygiene and Prevention should be presented to motivate the introduction of Ophtascan into our national health system to screen for type 2 diabetes nationwide.

5.2   CANCER AND PRECANCEROUS CONDITIONS

The low number detected cases do not allow solid conclusions to be drawn. In addition, given the difficulty to confirm all types of cancer mentioned above due to its high cost for patients, we recommend to carry out a new pilot research project which will focus on: "Validation of the 'Ophtascan to identify the risk of cervical cancer (#1 mortality for female cancers in the DRC with 12.7%)' for which early treatment is possible at a low cost in our environment. This project will be executed concurrently with the first one. In the event of a satisfactory result, the use of the test may be authorized.

What is known:

- Screening for cancer and type 2 diabetes

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What the study adds:

- Ophtascan as a new tool on cancer and type 2 diabetes
- Reliability of ophtascan in detecting type 2 diabetes
- Early Detection of cervical, uterus, breast, prostate, lung cancer by ophtascan

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