RWD25

External Validity and Representativeness of Telotron® Database: A Reliable Source for Real-World Evidence Research in Spain

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Conclusions

- The Spanish TELOTRON® database effectively mirrors the Spanish population in demographic and health-related data with respect to the data sources consulted (INE, BDCAP and Ministry of Health data) as demonstrated by its alignment.
- TELOTRON ® is shown as a reliable source for real-world evidence research in Spain in terms of representativeness and external validity of its records.

Introduction

- Databases integrating electronic medical records (EMRs) offer great potential for observational epidemiological research and evidence generation, as well as complementing traditional randomized controlled trials.
- TELOTRON® database encompasses longitudinal data from primary care, specialists, hospital and emergency units from approximately 2.2 anonymized patients from the Spanish National Health System since 2012 until present.

Objectives

This study evaluates the population representativeness and external validity of TELOTRON® as a secondary data source for retrospective observational research.

Methods

- An observational-retrospective study was carried out to compare TELOTRON® RWD to the most updated Spanish official sources.
- Population representativeness was assessed comparing TELOTRON®'s demographic distribution to 2022 Spanish population data from the National Institute of Statistics (INE).
- External validity was evaluated both by comparing disease prevalences found in TELOTRON® to the Spanish National Health System (BDCAP) report published in December 2023. And by comparing medication dispensation data within TELOTRON® and 2023 Spanish Ministry of Health report on drug consumption prescribed within the National Health System.
- The health conditions compared to BDCAP report were arterial hypertension, diabetes, dyslipidemia, asthma, COPD, depressive syndrome, hypothyroidism, osteoporosis, ischemic heart disease, cerebrovascular disease and heart failure. Pathologies within TELOTRON® are codified in ICD-9 and ICD-10 and were mapped to CIAP2 to match BDCAP pathologies criteria.
- Medication dispensation were compared using the levels of Anatomical Therapeutic Chemical Classification (ATC).
- Descriptive statistics and Pearson's correlation were used to determine concordances.

Results

- The distribution of the population (by age ranges and sex) present in the TELOTRON® database was comparable to the Spanish population (r=0.971), with an average absolute difference of 0.2 points (Figure 1). The biggest difference is shown in the 0-4 age range (1.8 points).
- In the comparison of prevalences of TELOTRON® vs. BDCAP, the average difference was 0.96 points and a median of 0.46 (Table 1).
- Depressive syndrome showed the greatest difference (4.7% BDCAP; 9.8% TELOTRON®), followed by hypothyroidism (6.4% BDCAP; 4.5% TELOTRON®).
- The most prevalent diseases were dyslipidemia (21.5% BDCAP; 22.4% TELOTRON®) and arterial hypertension (18.4% BDCAP; 17.7% TELOTRON®), and the least prevalent heart failure (1.2% BDCAP; 1.3% TELOTRON®).
- Prescription data showed strong correlation with Ministry of health data, r=0.997 (ATC1), r=0.994 (ATC2) and r=0.982 (ATC3), with an average difference of 0.50% (Figures 2 & 3). The biggest difference was observed in the therapeutic group A02 Drugs for acid related disorders (1.8%).

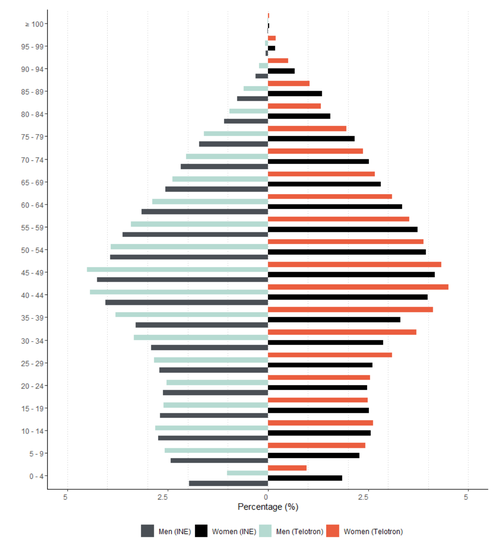

Figure 1. Age and sex demographics of TELOTRON® active patients in 2022 compared to 2022 Spanish population per National Institute of Statistics.

	BDCAP	TELOTRON®	Diference (absolute)
Arterial Hypertension	**18.4 %**	**17.7 %**	0.7
Diabetes	**7.5 %**	**7.3 %**	0.2
Hypercholesterolemia	**21.5 %**	**22.4 %**	0.9
Asthma	**7.4 %**	**6.9 %**	0.5
COPD	**2.2 %**	**2.4 %**	0.2
Depression	**4.7 %**	**9.8 %**	5.1
Hypothyroidism	**6.4 %**	**4.5 %**	1.9
Osteoporosis	**3.1 %**	**3.0 %**	0.1
Ischemic heart disease	**2.3 %**	**2.7 %**	0.4
Stroke	**1.6 %**	**2.1 %**	0.5
Heart failure	**1.2 %**	**1.3 %**	0.1

Table 1. Prevalence of chronic diseases in TELOTRON® in year 2021 compared to BDCAP. Report of Spanish National Health System, BDCAP was published in December 2023 with data belonging to 2021.

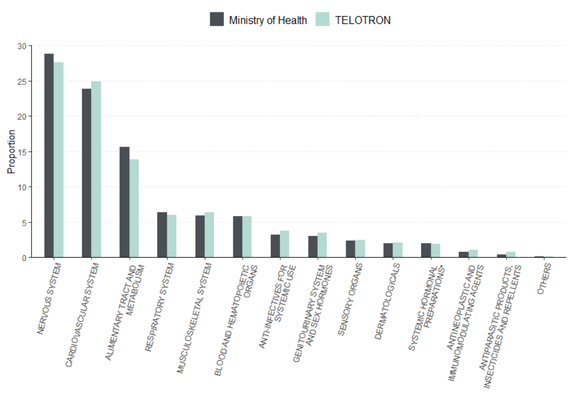

Figure 2. Proportion of prescribed drugs based on ATC1 at TELOTRON® compared to Spanish Ministry of Health's data for year 2023. Data arranged in descending order of proportion.

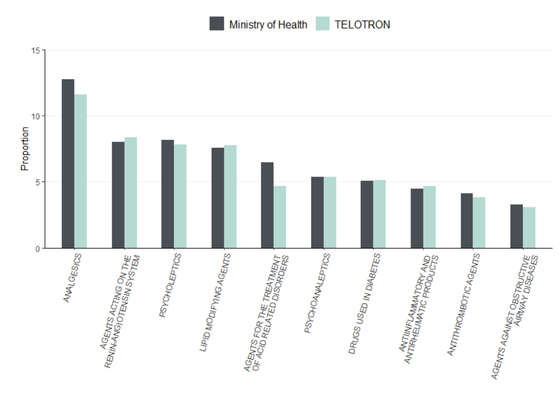

Figure 3. Proportion of the most prescribed drugs based on ATC2 at TELOTRON® compared to Spanish Ministry of Health's data for year 2023. Data arranged in descending order of proportion.

Abbreviations: RWD: Real World Data **INE:** Instituto Nacional de Estadística; **BDCAP:** Base de Datos Clínicos de Atención Primaria; **ICD:** International Statistical Classification of Diseases and Related Health Problems; **CIAP:** Clasificación Internacional de Atención Primaria; **ATC:** Anatomical Therapeutic Chemical Classification System; **COPD:** Chronic Obstructive Pulmonary Disease

Official sources used for TELOTRON® comparison:

1. Instituto Nacional de Estadística (INE) 2022. Población por edad y sexo (grupos quinquenales) https://www.ine.es/jaxi/Tabla.htm?path=/t20/e245/p08/l0/&file=01002.px&L=0. Accessed: 21/03/2024.
2. Ministerio de Sanidad. Informe Anual del Sistema Nacional de Salud 2022. Informes, estudios e investigación, 2023. Base de Datos Clínicos de Atención Primaria (BDCAP) https://www.sanidad.gob.es/estadEstudios/estadisticas/sisInfSanSNS/tablasEstadisticas/InfAnualSNS2022/INFORME_ANUAL_2022.pdf. Accessed: 21/03/2024
3. Sistema Nacional de Salud. Caracterización de los problemas de salud no transmisibles a partir de los registros clínicos de atención primaria (BDCAP). BDCAP-Series 5 Datos 2021. Publication december 2023. https://www.sanidad.gob.es/estadEstudios/estadisticas/estadisticas/estMinisterio/SIAP/Caracterizacion_problemas_salud_no_transmisibles.pdf. Consultado: 21/03/2024.
4. Ministerio de Sanidad. Consumo de medicamentos en recetas médicas dispensadas en oficinas de farmacia con cargo al Sistema Nacional de Salud según clasificación Anatómica-Terapéutica-Química (ATC) en 2023 Ministerio de Sanidad - Áreas - Datos mensuales y anuales de consumo de recetas médicas según clasificación ATC - Año 2023 Accessed: 21/03/2024.
5. Clasificación Internacional de Atención Primaria. CIAP2 .Mapeo a CIE9 y CIE 10. https://www.sanidad.gob.es/estadEstudios/estadisticas/estadisticas/estMinisterio/SIAP/map_cie9mc_cie10_ciap2.htm
6. The Anatomical Therapeutic Chemical Classification System with Defined Daily Doses (ATC/DDD): World Health Organization https://atcddd.fhi.no/atc_ddd_index/. Accessed: 21/03/2024.

Poster link

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