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ORIGINAL ARTICLES

Rotavirus vaccination efficacy in a real-world scenario: a 10-year experience from a secondary hospital in Portugal

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ABSTRACT

Introduction: Although recommended, the rotavirus vaccine is not included in Portugal's routine immunization schedule. This provides an opportunity to evaluate its real-world effectiveness. This study aimed to assess the impact of rotavirus vaccination on reducing infection rates and hospitalizations."

Material and Methods: This retrospective study examined all pediatric patients who underwent viral antigen stool testing at our hospital between 2012 and 2022. Patients were classified as either rotavirus-positive or rotavirus-negative. Data on vaccination status and hospitalization were obtained from electronic medical records. A control group, matched in size to the rotavirus-positive group, was randomly selected from the rotavirus-negative patients (N= 126)."

Results: Out of 886 viral antigen stool tests performed, 126 (14.2%) returned positive for rotavirus. The median age in the rotavirus-positive group was 16 months (IQR 6–24), compared to 12 months (IQR 4–29) in the negative group. A total of 81 patients (32%) were vaccinated, with a vaccination rate of 15% (N=19) in the positive group and 49% in the negative group (n=62).

Vaccination was linked to a lower number of infections (OR 0.18–0.34) and a reduced hospitalization rate (OR 0.23–0.43). The vaccine's efficacy beyond the first year of life was also assessed.

Conclusions: This study demonstrates the effectiveness of the rotavirus vaccination in preventing infection and hospitalization at our hospital. These results highlight the importance of considering the inclusion of the rotavirus vaccine in the routine immunization schedule.

Keywords: gastroenteritis; rotavirus; vaccine

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INTRODUCTION

Before the introduction of vaccines, rotavirus was the leading cause of gastroenteritis, responsible for over two million hospitalizations and 440,000 deaths each year worldwide. The introduction of vaccines transformed this situation, resulting in a significant decrease in hospitalization and death rates with recent studies estimating that global use of rotavirus vaccines could prevent about 37% of rotavirus deaths in children under 5.[1] As a result, the vaccine has been included in the national immunization programs of nearly 90% of the countries participating in the Global Alliance for Vaccines and Immunization.[2]

Despite recommendations from WHO and the vaccination commission of the Portuguese Society of Pediatrics, the rotavirus vaccine has not been incorporated into Portugal's routine immunization schedule for all children.[3] As a result, there is variability in vaccination rates across different regions.

Assessing the real-world vaccine effectiveness (VE) is essential for confirming its benefits and aiding policymakers in developing immunization strategies. While the earliest VE studies were conducted in countries with low child mortality rates, the introduction of the vaccine in high child mortality settings has enabled VE studies in those regions as well.

Although the vaccines demonstrated effectiveness across all settings, recent evidence indicates substantially higher efficacy in countries with lower child mortality. Estimated vaccine efficacy ranged from 69.6% to 94.3% in low-mortality settings and from 18.6% to 85.3% in high-mortality regions.[4] Some studies have also shown a reduction in vaccine effectiveness (VE) during the second year of life, underscoring the importance of expanding vaccine protection beyond the first year. However, further studies have revealed that this decline is primarily limited to children who are HIV-exposed or chronically malnourished.[5]

Considering all the variables that influence vaccine effectiveness (VE), the aim of this study was to assess the vaccination rate in our pediatric population and evaluate its efficacy in reducing infection and hospitalization rates. Additionally, we aimed to determine whether there is a decline in VE beyond the first year of life.

MATERIAL AND METHODS

A retrospective study was conducted, including all pediatric patients who underwent viral antigen stool test performed using enzyme-linked immunosorbent assay (ELISA) at our hospital from 2012 to 2022. These tests were performed either in the emergency department or during a hospital admission. Antigen test results were obtained with the assistance of the pathology and microbiology departments. Patients were then categorized in two groups (either positive or negative for rotavirus). From the pool of patients that had negative stool test (n= 760) a stratified random sampling with the same number of patients as the positive group was performed, ensuring proportional representation by age and gender. Electronic medical records were used to access information on vaccination status, hospitalizations and length of stay. Exclusion criteria were inability to access the vaccination record and/or medical records.

Statistical analyses were conducted using IBM® SPSS® Statistics, version 29.0 (IBM Corp., Armonk, NY, USA). Chi-square tests were performed to assess the presence of statistically significant differences between groups. To assess vaccine effectiveness (VE) in children after their first year of life, we analyzed those older than 12 months in both groups (n= 136)

RESULTS

A total of 886 viral antigen stool tests were conducted, of which 126 (14.2%) tested positive for rotavirus. The percentage of male patients was the same in both groups, at 55% (n=69). The median age was 16 months (IQR 6–24) for the positive group and 12 months (IQR 4–29) for the negative group.

The vaccination rate in the analyzed population (n=252) was 32% (n=81), with the rate in the positive group decreasing to 15% (n=19) and increasing to 49% (n=62) in the negative group (**Figure 1**).

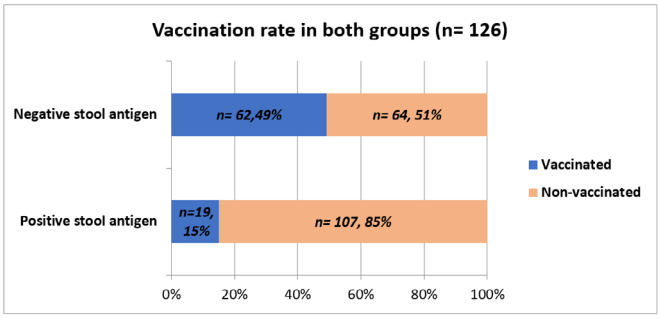

Figure 1 - Vaccination rate in both groups

When comparing vaccinated and unvaccinated individuals, vaccination was associated with a reduced risk of testing positive for the antigen (OR 0.183; 95% CI 0.101 – 0.334; p<0.0001). Among the unvaccinated patients, 63% (n=79) tested positive, compared to only 23% (n=29) of those who were vaccinated.

Hospitalization was required for 100 patients, of whom 85% (n=85) were unvaccinated (**Figure 2**). The hospitalization rate was 50% (n=85) among the unvaccinated, compared to only 19% (n=15) in the vaccinated group (**Figure 3**). Thus, vaccination was associated with a significantly lower risk of hospitalization (OR 0.230; 95% CI 0.122–0.434; p<0.0001).

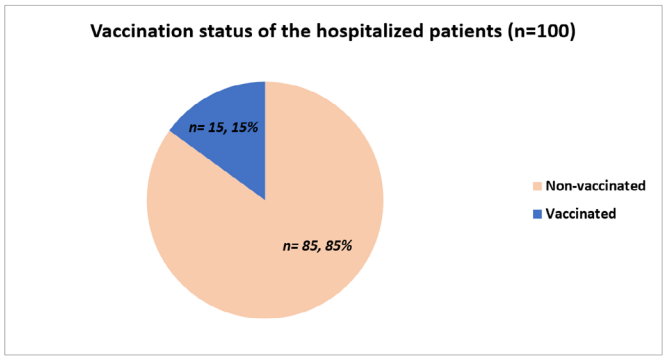

Figure 2 - Vaccination status of the hospitalized patients (n=100)

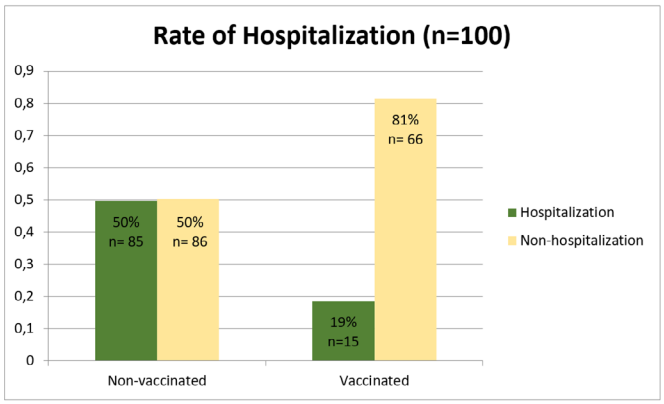

Figure 3 - Comparison of the rate of hospitalization between the non-vaccinated group (n= 171) versus the vaccinated group (n=81)

When evaluating the sub-group of patients older than 12 months (N= 136), we found a vaccination rate of 32% (n=43). From the group that was vaccinated only 20% were hospitalized versus 47% in those non-vaccinated translating a reduced likelihood of hospital admission (OR 0.182; 95% CI 0.074–0.451; p<0.0001). Vaccination was also associated with a lower risk of infection (OR 0.130; 95% CI 0.057–0.301; p<0.0001) with only 20% of those vaccinated presenting a positive stool antigen versus 53% of those non-vaccinated.

DISCUSSION

The findings of this study provide evidence for the efficacy of the rotavirus vaccine in reducing both the incidence of infection and hospitalization due to rotavirus-related illnesses.

This study has several limitations that should be acknowledged. Its retrospective and single-center design limits the generalizability of the findings and introduces potential information bias due to reliance on existing medical records, which may be incomplete or inconsistent. The sample size, although spanning a ten-year period, was relatively small, which may reduce statistical power, particularly for subgroup analyses. Furthermore the high hospitalization rate observed in our sample may, in part, be explained by a selection bias inherent to clinical testing practices. In many settings, stool antigen testing for rotavirus is more likely to be performed in cases presenting with more severe symptoms, particularly those warranting hospital admission. Milder cases of acute gastroenteritis are frequently managed in outpatient settings without laboratory confirmation, leading to underrepresentation of less severe cases in our dataset. Consequently, the sample may overestimate the proportion of hospitalizations relative to the broader population of rotavirus infections.[6]

By substantially decreasing the incidence of rotavirus infection, the vaccine not only alleviates the disease burden on affected individuals but also reduces the strain on healthcare systems by lowering hospitalization rates.

In light of the findings presented in this study, it is important to highlight the relevance of extending the vaccination to the entire population. In Portugal this vaccine is currently only indicated for high-risk groups despite the recommendations of the portuguese pediatric infectious society of extending it.[7] Our results support the potential benefits of extending universal rotavirus vaccination, as they underscore the burden of disease and the likely public health impact of broader vaccine coverage.

Importantly, vaccine effectiveness (VE) was maintained even in children older than 12 months, consistent with studies indicating that a decline in effectiveness is primarily seen in malnourished or immunocompromised children.[8]

The low vaccination rate verified in our population indicates a poor adherence to non-routine immunization practices, underscoring the need to enhance vaccine access and awareness, along with incorporating the vaccine into the national immunization program.[9]

CONCLUSIONS

These results highlight the considerable public health implications of rotavirus vaccination efforts and the need for extensive vaccination initiatives. The significant decline in rotavirus infections observed in this study aligns with numerous other research findings and real-world vaccination campaigns, reinforcing the vaccine's effectiveness.

Its effectiveness combined with the low vaccination rate reinforces the importance of increasing awareness among both caregivers and healthcare practitioners and reiterates the importance of discussing its inclusion in the national immunization program.

AUTHORSHIP

João Nogueira Oliveira - Data curation; Formal analysis; Writing – original draft; Writing – review & editing
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Maria José Dinis – Writing – review & editing
Gracinda Nogueira Oliveira - Conceptualization

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