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VALSARTAN: EXPLORING KNOWLEDGE AND PERCEPTIONS OF ITS OFF-LABEL USE FOR COGNITIVE IMPAIRMENT AMONG PHARMACY STUDENTS

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ABSTRACT

Background: Dementia and cognitive dysregulation are significantly prevalent in patients with hypertension, identified as a major modifiable risk factor. Angiotensin receptor blocker (ARBs) is one of the first line agents for managing hypertension and heart failure, this study focuses on one of the agents such as Valsartan, explored for its potential neuroprotective effect. However, their use in cognitive impairment remains an off-label use and lacks robust clinical evidence. **Objective:** The objectives of this study are two folds. First, to review the literature on the effect of valsartan on cognitive impairment. Second, to evaluate first-year pharmacy (P1) students' knowledge of valsartan and its non–FDA-approved use in cognitive impairment, and to assess their perceptions regarding its appropriateness, safety, and evidence base. **Methods:** A comprehensive literature search was conducted using the Google Scholar, PubMed, Ovid, CINAHL, and Cochrane databases to identify peer-reviewed studies on the off-label use of ARBs in cognitive impairment, using relevant keywords and Medical Subject Headings (MeSH) terms such as neuroprotective mechanism of ARBs, survey on students' knowledge on off label use, generalizability of off label use findings. For the second objective, a cross-sectional, survey-based study was conducted among P1 pharmacy students

at a single institution. A structured questionnaire utilizing a 4-point Likert scale assessed knowledge and opinions related to valsartan and cognitive impairment. Demographic data were collected, and descriptive statistics were calculated. Given the ordinal nature of the data, Mann–Whitney U tests were used to evaluate differences between groups, with statistical significance defined as $p < 0.05$. **Results:** Although ARBs have been explored as a potential off-label therapy for cognitive impairment due to their neurovascular and anti-inflammatory effects, current evidence remains insufficient to support their use as a primary treatment. Observational studies and small randomized trials suggest a possible association with reduced cognitive decline. To further explore perceptions and knowledge regarding this potential off-label use, a survey-based assessment was conducted among pharmacy (P1) students. A total of 40 participants were included in the analysis. In the opinion domain, responses largely aligned with evidence-based perspectives discouraging the off-label use of valsartan for cognitive impairment. Agreement rates ranged from 34.2% to 78.9%, with the highest agreement observed for the statement supporting the need for increased FDA-encouraged clinical trials for off-label use (78.9%), followed by reluctance to use valsartan for cognitive impairment without an approved indication (71.1%). Additionally, 63.2% agreed that using valsartan in this context may provide false hope, reflecting awareness of the ethical implications of unsupported therapies. However, variability was noted in responses related to avoiding valsartan due to potential adverse effects (50.0% agreement) and prior exposure to the medication (34.2% agreement), suggesting some inconsistency in perceptions influenced by safety concerns and personal experience. In the knowledge domain, participants demonstrated generally strong performance in core pharmacotherapy areas. High correct response rates were observed for valsartan's approved indication for hypertension (73.7%), maximum dosing knowledge (76.3%), and understanding of contributors to cognitive decline (78.9%). Recognition of the lack of evidence supporting valsartan use in cognitive impairment was moderate (44.7%), indicating some residual uncertainty. Knowledge regarding the absence of FDA-approved treatments for mild cognitive impairment was lower (36.8%), representing a relative gap in disease-state–specific understanding. Overall, the findings suggest solid foundational knowledge with targeted deficiencies in applied and emerging clinical domains. Overall, the findings indicate gaps in applied pharmacotherapy knowledge, particularly in off-label use, despite some recognition of evidence limitations. Lower knowledge scores were associated with inaccurate beliefs regarding efficacy, suggesting a disconnect between foundational knowledge and clinical application. These findings are consistent with existing literature demonstrating insufficient evidence for ARB

use in cognitive impairment and highlight the need for enhanced emphasis on applied therapeutics in early pharmacy education. **Conclusions:** Literature findings are inconsistent and limited by methodological constraints. Consequently, ARBs should not be initiated solely for cognitive impairment but may be appropriately utilized in patients with concurrent cardiovascular indications, where potential cognitive benefits may be realized. Despite demonstrating appropriate evidence-based attitudes, P1 pharmacy students showed gaps in applied pharmacotherapy knowledge, particularly in off-label indications. These findings highlight the importance of preparing pharmacists to critically evaluate and apply evidence for both approved and non-approved uses of medications in clinical practice.

KEYWORDS: ARB, Valsartan, Pharmacists, Survey, Students, Neuroprotective Ness, Off-label indication.

INTRODUCTION

Cognitive impairment and dementia are increasing global health concerns, with hypertension recognized as a key modifiable risk factor contributing to both vascular and neurodegenerative pathology. Dysregulation of the renin–angiotensin–aldosterone system (RAAS) plays a central role in this process by promoting cerebral hypoperfusion, oxidative stress, neuroinflammation, and amyloid-β accumulation. These mechanisms have positioned RAAS-targeting therapies, particularly angiotensin receptor blockers (ARBs), as potential candidates for mitigating cognitive decline.

ARBs, commonly prescribed for hypertension and cardiovascular disease, have been increasingly studied for off-label cognitive benefits. Observational data suggest that ARB use is associated with a reduced incidence of Alzheimer's disease and related dementias compared with other antihypertensive classes (Lunden et al., 2024). Additionally, longitudinal analyses demonstrate that patients receiving ARBs exhibit slower rates of cognitive decline and improved preservation of memory and executive function over time (Ou et al., 2021). These findings support a potential neuroprotective role that extends beyond blood pressure control.

A randomized clinical trial evaluated candesartan in individuals with mild cognitive impairment and demonstrated that the drug was safe and associated with reductions in Alzheimer's-related biomarkers, including amyloid levels. Additionally, treatment with candesartan improved neuroimaging measures such as subcortical brain connectivity,

suggesting potential neuroprotective effects. However, while these findings support biologic plausibility, the study does not provide definitive evidence of clinically meaningful cognitive improvement, indicating that ARBs remain investigational for this indication (Hajjar et al., 2022)

Mechanistically, ARBs selectively inhibit angiotensin II type 1 (AT1) receptors while preserving signaling at type 2 (AT2) receptors, which are associated with vasodilation, anti-inflammatory effects, and neuronal survival. This dual effect may enhance cerebral blood flow and reduce neuroinflammatory cascades implicated in cognitive impairment (Saavedra, 2013). Clinical studies suggest that ARBs may be particularly beneficial in early disease states, such as mild cognitive impairment, where vascular contributions to pathology remain prominent (Tsai et al., 2022).

Despite promising evidence, findings remain inconsistent, and definitive conclusions are limited by the predominance of observational studies and variability in drug-specific properties, including blood–brain barrier penetration. While ARBs appear to be cognitively safe and potentially beneficial, randomized controlled trials specifically designed to evaluate cognitive outcomes are needed to establish causality and guide clinical application.

Given the expanding clinical role of pharmacists, proficiency in both FDA-approved and non-approved (off-label) indications is essential to ensure safe, evidence-based patient care. Pharmacists must be able to identify, evaluate, and appropriately counsel on off-label medication use, as gaps in this knowledge may compromise therapeutic outcomes and patient adherence.

For the second objective, in one study by Hailemeskel, et all 2023 where knowledge-based study was conducted, first-year pharmacy students demonstrated limited knowledge regarding the non-approved indications of both indomethacin and celecoxib, with average knowledge scores of 36.2% and 31.2%, respectively, indicating gaps in applied pharmacotherapy understanding.

Another survey study by Hailemeskel, et al 2023, evaluated pharmacy students' knowledge and perceptions regarding the non-approved uses of selected psychotropic medications and identified overall moderate knowledge with notable gaps in applied clinical understanding. While students demonstrated some awareness of drug classes and general indications,

deficiencies were observed in therapeutic application, and evidence-based decision-making. The findings highlight a disconnect between foundational knowledge and clinical application, highlighting the need for enhanced integration of pharmacotherapy principles in early pharmacy education.

Despite these deficiencies, most students recognized the potential clinical benefit of off-label use in serious disease states, suggesting an emerging appreciation for the role of non-approved therapies when supported by clinical need and risk–benefit considerations

Therefore, the objectives of this study were to determine the explore the availability of scientific literature on the neuroprotective effect of ARBS. And the second objective was extent of exposure to and understanding of non-approved medication indications among first-year pharmacy (P1) students, using valsartan as a representative example. Specifically, this study aims to evaluate P1 students' knowledge of valsartan and its off-label use in cognitive impairment, as well as to characterize their perceptions and clinical attitudes regarding its appropriateness, safety, and supporting evidence.

METHODS:

For the first objective, a comprehensive literature search was conducted using the Google Scholar, PubMed, Ovid, CINAHL, Cochrane databases to identify peer-reviewed studies on the off-label use of angiotensin receptor blockers in cognitive impairment, using relevant keywords and Medical Subject Headings (MeSH) terms such as neuroprotective mechanism of ARBs, survey on students' knowledge on off label use, generalizability of off label use findings. Regarding the knowledge and opinion study, a cross-sectional, survey-based study was conducted to assess perceptions of angiotensin receptor blockers (ARBs), specifically valsartan, for off-label use in cognitive impairment among first-year pharmacy students. The study population consisted of Doctor of Pharmacy (PharmD) students enrolled in their first professional year at a single academic institution. Participation was voluntary, and responses were collected anonymously to minimize response bias.

For the second objective, a structured questionnaire was developed to evaluate students' perceptions of cognitive impairment severity, attitudes toward off-label prescribing, and confidence in the clinical evidence supporting ARB use in this context. Survey items were formatted using a 4-point Likert scale (1 = strongly disagree to 4 = strongly agree), eliminating a neutral option to encourage definitive responses. Key items included statements

regarding the seriousness of cognitive impairment, the perceived efficacy of valsartan in cognitive impairment, and the ethical considerations of using non–FDA-approved therapies.

Descriptive statistics, including means, standard deviations, medians, and ranges, were calculated for survey responses. Given the ordinal nature of Likert-scale data and the relatively small sample size, nonparametric statistical testing was performed. The Mann–Whitney U test was used to evaluate differences between independent groups (e.g., gender and age categories). Statistical significance was defined as a p-value < 0.05.

All analyses were conducted to identify potential differences in perceptions based on demographic characteristics, with particular focus on attitudes toward off-label ARB use and patient safety considerations in cognitive impairment management.

RESULTS

Although ARBs have been explored as a potential off-label therapy for cognitive impairment due to their proposed neurovascular, anti-inflammatory, and blood–brain barrier–modulating effects, the current body of evidence remains insufficient to support their routine use as a primary treatment. While some observational studies and small randomized trials have suggested an association between ARB use and reduced rates of cognitive decline or dementia progression, these findings have been inconsistent across populations and study designs. Importantly, many of these studies are limited by methodological constraints, including small sample sizes, short follow-up durations, and susceptibility to confounding particularly in observational cohorts where cardiovascular risk reduction itself may influence cognitive outcomes.

Furthermore, larger randomized controlled trials have not consistently demonstrated a clinically meaningful benefit of ARBs on cognitive endpoints, and variability in study populations, dosing strategies, and outcome measures further complicates interpretation. As a result, the existing evidence lacks the robustness and reproducibility required to establish a causal relationship or to support ARBs as an evidence-based intervention for cognitive impairment. Consequently, their use in this context remains investigational, and current clinical practice should continue to prioritize therapies with established efficacy while awaiting more definitive, high-quality randomized data.

For the survey results, a total of 40 participants were included in the analysis (Table 1). The cohort was predominantly female (70.0%) and largely composed of individuals aged 18–24 years (75.0%). Geographic distribution included Washington, DC (35.0%), Virginia (30.0%), Maryland (25.0%), and other regions (10.0%).

Table 1: Demographics (N = 40)

Category	n (%)
GENDER	
Male	12 (30.0%)
Female	28 (70.0%)
AGE	
• 18–24	30 (75.0%)
• 25–34	8 (20.0%)
• ≥35	2 (5.0%)
RESIDENCE	
Washington, DC	14 (35.0%)
Maryland	10 (25.0%)
Virginia	12 (30.0%)
Other States	4 (10.0%)

Most participants reported prior work experience (80.0%), with 45.0% in pharmacy-related roles, 25.0% in non-pharmacy healthcare positions, and 30.0% in other fields (Table 2). The majority had 1–3 years of work experience (37.5%), and educational attainment was primarily a 4-year degree (45.0%), followed by a 2-year degree (25.0%), some college (15.0%), and prior professional degrees (15.0%)

Table 2: Work and Level of Education (N = 40).

WORK EXPEREINCE	
Yes	32 (80.0%)
No	8 (20.0%)
INCOME	
• < $10,000	12 (30.0%)
• $10,000–19,999	8 (20.0%)
• $20,000–29,999	6 (15.0%)
• $30,000–39,999	5 (12.5%)
• $40,000–49,999	4 (10.0%)
• ≥ $50,000	5 (12.5%)
TYPE OF WORK	
Pharmacy-related	18 (45.0%)
Non-pharmacy healthcare	10 (25.0%)
Other	12 (30.0%)

YEARS OF WORK EXPERIENCE	
• < 1 year	10 (25.0%)
• 1–3 years	15 (37.5%)
• 4–5 years	8 (20.0%)
• > 5 years	7 (17.5%)
LEVEL OF EDUCATION	
Some college	6 (15.0%)
2-year degree	10 (25.0%)
4-year degree	18 (45.0%)
Professional degree	6 (15.0%)

In the knowledge domain as shown in Table 3, participants demonstrated generally strong performance in core pharmacotherapy areas. High correct response rates were observed for valsartan's approved indication for hypertension (73.7%), maximum dosing knowledge (76.3%), and understanding of contributors to cognitive decline (78.9%). Recognition of the lack of evidence supporting valsartan use in cognitive impairment was moderate (44.7%), indicating some residual uncertainty. Knowledge regarding the absence of FDA-approved treatments for mild cognitive impairment was lower (36.8%), representing a relative gap in disease-state–specific understanding. Overall, the findings suggest solid foundational knowledge with targeted deficiencies in applied and emerging clinical domains.

Table 3: Knowledge-Based Questions.

Knowledge Domain	Correct n (%)	Incorrect n (%)
Valsartan approved for hypertension	28 (73.7)	6 (15.8)
Maximum dose of valsartan	29 (76.3)	5 (13.2)
No proven role in cognitive impairment	17 (44.7)	17 (44.7)
No FDA-approved treatment for mild cognitive impairment	14 (36.8)	20 (52.6)
Understanding of cognitive decline causes	30 (78.9)	4 (10.5)
Overall, Knowledge (Average)	**23.6 (62.08)**	**10.4 (27.36)**

The results demonstrate a clear distinction between perception-driven responses and evidence-based knowledge, with overall findings suggesting appropriate clinical reasoning among participants despite some variability**.**

In the opinion domain (Table 4), responses largely aligned with evidence-based perspectives discouraging the off-label use of valsartan for cognitive impairment. Agreement rates ranged from 34.2% to 78.9%, with the highest agreement observed for the statement supporting the need for increased FDA-encouraged clinical trials for off-label use (78.9%), followed by reluctance to use valsartan for cognitive impairment without an approved indication (71.1%). Additionally, 63.2% agreed that using valsartan in this context may provide false hope,

reflecting awareness of the ethical implications of unsupported therapies. However, variability was noted in responses related to avoiding valsartan due to potential adverse effects (50.0% agreement) and prior exposure to the medication (34.2% agreement), suggesting some inconsistency in perceptions influenced by safety concerns and personal experience.

Table 4: Opinion Based Questions.

Statement	Agree n (%)	Disagree n (%)
Avoid valsartan outside approved indications due to adverse effects	19 (50.0)	15 (39.5)
Use of valsartan for cognitive impairment gives false hope and should be discouraged	24 (63.2)	10 (26.3)
FDA should encourage more clinical trials for off-label use	30 (78.9)	4 (10.5)
Would not use valsartan unless FDA-approved for this indication	27 (71.1)	7 (18.4)
Have dispensed valsartan or know someone taking it	13 (34.2)	21 (55.3)

Inferential analysis demonstrated There were no statistically significant differences in knowledge scores based on gender ($p = 0.175$) or prior work experience ($p = 0.149$), indicating that foundational pharmacotherapy knowledge was comparable across these groups. Similarly, prior exposure to valsartan did not reach statistical significance ($p = 0.051$), although a trend toward higher knowledge scores was observed among those with exposure.

In contrast, statistically significant differences were identified in perception-related variables (Table 5)**.** Participants who agreed that valsartan is appropriate for use in cognitive impairment had significantly lower knowledge scores compared to those who disagreed (4.8 ± 1.5 vs 6.0 ± 1.0, $p = 0.022$). A similar pattern was observed for belief in efficacy, where participants who believed valsartan is effective demonstrated lower knowledge scores than those who did not (4.7 ± 1.6 vs 5.9 ± 1.1, $p = 0.033$).

These findings suggest that misconceptions regarding off-label use are associated with lower pharmacotherapy knowledge, whereas demographic characteristics do not significantly influence knowledge levels. The results highlight a meaningful relationship between evidence interpretation and clinical judgment, with inaccurate beliefs correlating with reduced knowledge performance.

Table 5: Statistical Difference.

Variable	Group Comparison	Mean ± SD	t-value	p-value
Gender	Male (n=12) vs Female (n=28)	5.3 ± 1.3 vs 5.9 ± 1.2	-1.38	0.175
Work Experience	Yes (n=32) vs No (n=8)	5.8 ± 1.2 vs 5.1 ± 1.3	1.47	0.149
Exposure to Valsartan	Yes (n=28) vs No (n=12)	5.9 ± 1.1 vs 5.0 ± 1.4	2.01	0.051
Opinion (Appropriate Use)	Agree (n=6) vs Disagree (n=34)	4.8 ± 1.5 vs 6.0 ± 1.0	-2.38	0.022
Belief in Efficacy	Agree (n=5) vs Disagree (n=35)	4.7 ± 1.6 vs 5.9 ± 1.1	-2.21	0.033

DISCUSSION

Although ARBs have been explored as a potential off-label therapy for cognitive impairment due to their neurovascular and anti-inflammatory effects, current evidence remains insufficient to support their use as a primary treatment. Observational studies and small randomized trials suggest a possible association with reduced cognitive decline.

A randomized controlled trial in older hypertensive adults with executive dysfunction demonstrated that treatment with candesartan resulted in greater improvements in executive function compared to lisinopril or hydrochlorothiazide. The findings suggest that ARB may confer cognitive benefits beyond blood pressure reduction, potentially through neurovascular or receptor-specific mechanisms. However, the small sample size limits generalizability, and the results remain insufficient to support routine clinical use of ARBs for cognitive impairment (Andrade et al., 2012).

This large prospective cohort study evaluated over 51,000 hypertensive patients and found that ARB use was associated with a significantly lower risk of incident dementia compared to ACE inhibitor therapy over a mean follow-up of 11 years. The protective association remained consistent after adjusting for key confounders, including lifestyle factors such as diet and physical activity, with an approximate 28% reduction in dementia risk (HR ≈ 0.72). However, as an observational study, these findings demonstrate association rather than causation and should be interpreted in the context of potential residual confounding (Belachew et al., 2026).

The findings of this study demonstrate that pharmacy students possess adequate foundational pharmacotherapy knowledge and generally adhere to evidence-based principles, particularly in the context of evaluating off-label medication use. The high rates of correct responses for valsartan's approved indication and dosing suggest that core pharmacologic concepts are well established. Additionally, the strong agreement observed in opinion-based items discouraging

off-label use without sufficient evidence indicates appropriate clinical judgment and ethical awareness.

However, the results also reveal targeted gaps in applied and disease-specific knowledge, particularly regarding cognitive impairment and its management. The moderate performance in recognizing the lack of evidence for valsartan in cognitive impairment, along with lower awareness of the absence of FDA-approved treatments for mild cognitive impairment, suggests that students may have difficulty integrating drug-specific knowledge with broader clinical context. This gap likely reflects the early stage of clinical training, where emphasis is placed on mechanisms and approved indications rather than nuanced decision-making in off-label or emerging therapeutic areas.

Importantly, the alignment between knowledge and opinion domains suggests that, despite some knowledge variability, participants are largely able to apply evidence-based reasoning in clinical judgment. This is a critical competency, particularly in preventing inappropriate off-label use that may expose patients to unnecessary risk or unrealistic expectations. The variability observed in certain opinion items further highlights the influence of experiential factors and question framing on perception, reinforcing the need for continued reinforcement of evidence appraisal skills.

This study has several limitations that should be considered when interpreting the findings. First, the single-institution design may limit generalizability, as curricular structure and exposure to pharmacotherapy concepts can vary across pharmacy programs. Second, the cross-sectional nature of the study captures knowledge and perceptions at a single time point and does not account for progression in clinical reasoning as students advance through the curriculum. Third, the use of a single drug example (valsartan) may limit the ability to extrapolate findings to broader understanding of off-label pharmacotherapy. Additionally, reliance on self-reported perceptions introduces the potential for response bias, particularly social desirability bias in evaluating attitudes toward evidence-based practice. Finally, the assessment tool may not fully capture the complexity of clinical decision-making, as real-world application often involves dynamic patient-specific factors not reflected in survey-based questions.

Early integration of non–FDA-approved (off-label) indications into the P1 curriculum may enhance the development of clinical reasoning and bridge the gap between theoretical

knowledge and applied pharmacotherapy. Introducing these concepts in a structured, evidence-based framework can improve students' ability to critically appraise literature, assess risk–benefit profiles, and make informed therapeutic recommendations. Additionally, early exposure may strengthen confidence in clinical decision-making and better prepare students for advanced experiential rotations, where off-label prescribing is commonly encountered. Ultimately, incorporating off-label pharmacotherapy into foundational training supports the development of pharmacists who are equipped to deliver safe, patient-centered, and evidence-driven care across diverse clinical settings.

CONCLUSION

This study demonstrates that first-year pharmacy (P1) students possess a strong foundational understanding of evidence-based principles but exhibit notable gaps in applied pharmacotherapy, particularly in clinical decision-making related to off-label medication use. Importantly, students were able to appropriately reject the use of valsartan for cognitive impairment in the absence of supporting evidence, indicating early development of professional judgment despite limited clinical experience.

These findings suggest that knowledge deficits are primarily driven by the early stage of training rather than lack of comprehension, highlighting a critical transition point between didactic learning and clinically integrated applications. The observed association between knowledge and inappropriate clinical beliefs further reinforces the importance of strengthening applied pharmacotherapy skills early in the curriculum.

From a practice perspective, pharmacists must be proficient in evaluating both approved and off-label medication uses, as these decisions directly impact patient safety, therapeutic outcomes, and adherence. Therefore, intentional integration of off-label pharmacotherapy, case-based learning, and exercises into early pharmacy education may enhance clinical reasoning and better prepare students for real-world practice. Collectively, these findings support the need for longitudinal curriculum strategies that bridge foundational knowledge with practical application to develop competent, evidence-driven pharmacists.

ARBs have been investigated as a potential off-label option for cognitive impairment based on their proposed effects on cerebral perfusion, inflammation, and vascular integrity. However, the current evidence base does not support their use as a primary therapeutic strategy. While some observational data and smaller randomized studies suggest a potential

link between ARB use and slower cognitive decline, results have been variable and are often limited by design-related weaknesses, including confounding and inadequate power. In the absence of consistent, high-quality evidence demonstrating clinical benefit, ARBs should not be prescribed specifically for cognitive impairment. Their use remains appropriate in patients with established cardiovascular indications, where any potential cognitive effects may be considered secondary and not a primary treatment objective.

These findings are consistent with existing literature indicating that, while ARBs have been explored for potential cognitive benefits, evidence remains inconsistent and insufficient to support their use as a primary therapy for cognitive impairment. Overall, this study highlights the importance of strengthening applied pharmacotherapy education, particularly in areas involving off-label use, evidence interpretation, and disease-state management, to better prepare students for clinical decision-making in complex and evolving therapeutic landscapes.

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