International Journal of Clinical Science and Medical Research

ISSN(print): 2770-5803, ISSN(online): 2770-582X

Volume 06 Issue 04 April 2026

DOI: https://doi.org/10.55677/IJCSMR/V6I4-04/2026, Impact Factor: 8.005

Page No : 97-110

AI-Based Protocol Assistant in Pelvic Floor Ultrasonography: Development and Impact on Workflow Adherence and Efficiency

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ABSTRACT

Background: Pelvic floor ultrasonography (PFUS) is a highly operator-dependent imaging modality in which variability in image acquisition, procedural sequencing, and documentation may reduce diagnostic reliability and reproducibility. Although standardized protocols are available, consistent real-time implementation remains challenging. Artificial Intelligence (AI) has increasingly been explored as a workflow-support tool to improve standardization and reduce operator dependency in medical imaging.

Objective: This study aimed to develop and evaluate an AI-based Protocol Assistant to support structured workflow execution in pelvic floor ultrasonography.

Methods: This study used a Research and Development approach with a modified 4D model limited to the Define, Design, and Develop stages. The system was designed to translate standardized PFUS protocols into stepwise procedural guidance integrated with workflow control and structured documentation. Feasibility was assessed through expert validation using Aiken's V coefficient. Initial functional evaluation employed a one-group pretest-posttest design involving 50 sonographers performing examinations without and with system assistance. Outcomes included protocol adherence and examination time. Data were analyzed descriptively and with the Wilcoxon Signed-Rank Test.

Results: The system demonstrated very high content validity, with Aiken's V values of at least 0.98 across all evaluated components. Protocol adherence improved significantly, with protocol loss decreasing from 16.7% without system assistance to 0.0% with the Protocol Assistant ($p < 0.05$). Examination time was also significantly reduced after implementation ($p < 0.05$).

Conclusion: The AI-based Protocol Assistant showed strong preliminary feasibility as a workflow-support system for PFUS, improving protocol adherence and examination efficiency. Further studies are needed to assess diagnostic accuracy, reproducibility, and generalizability across clinical settings.

Published Online: April 23, 2026

KEYWORDS:

pelvic floor ultrasonography, artificial intelligence, workflow support, protocol adherence, examination efficiency, medical imaging standardization

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***Cite this Article:** Istiqomah, H., Fatmasari, D., Hariri, A., Masrochah, S., Wibowo, G.M. (2026). AI-Based Protocol Assistant in Pelvic Floor Ultrasonography: Development and Impact on Workflow Adherence and Efficiency. International Journal of Clinical Science and Medical Research, 6(4), 97-110. https://doi.org/10.55677/IJCSMR/V6I4-04/2026*

INTRODUCTION

Pelvic floor ultrasonography (PFUS) has emerged as an increasingly important imaging modality in contemporary diagnostic radiology, particularly in urogynecology, obstetrics, and female pelvic medicine. Its clinical value lies in its non-invasive character, real-time visualization capacity,

relatively low cost, and ability to assess both anatomical structures and dynamic pelvic floor function during rest, contraction, and Valsalva maneuvers (Pugliesi et al., 2025; Zhu et al., 2024; Li et al., 2025). Unlike static imaging techniques, PFUS enables direct observation of pelvic floor movement and functional relationships among pelvic organs, which is essential in the assessment of pelvic organ prolapse, levator ani abnormalities, and hiatal measurements. However, the utility of PFUS is inseparable from the quality of its acquisition process. The examination is not merely a matter of capturing images, but of obtaining the correct imaging plane, maintaining appropriate probe orientation, recognizing relevant landmarks, and ensuring that dynamic maneuvers are performed consistently. For this reason, PFUS is widely recognized as an operator-dependent modality in which technical execution strongly influences image quality and interpretability. The problem is not trivial, because poor acquisition can propagate into inaccurate measurements, incomplete documentation, and unreliable clinical interpretation. As a result, the methodological rigor of the scanning process becomes as important as the diagnostic interpretation itself.

The literature consistently shows that operator dependency is one of the central methodological challenges in PFUS. Previous studies have demonstrated that variability in pelvic floor imaging may arise from differences in patient positioning, probe placement, image plane selection, timing of image capture, and the operator's ability to guide functional maneuvers such as straining and contraction (Pugliesi et al., 2025; Serati et al., 2022; Li et al., 2025). This variability becomes even more pronounced in three-dimensional and four-dimensional PFUS, where the assessment of hiatal area, anterior-posterior diameter, and levator ani muscle integrity demands high consistency in both acquisition and interpretation (Spinelli et al., 2021; Zhu et al., 2024; Weinstein et al., 2021). Several studies have reported that interobserver and intraobserver differences remain substantial when imaging protocols are not strictly standardized. In practical terms, two sonographers may examine the same patient but obtain different measurements because of subtle differences in probe angulation, landmark recognition, or the patient's Valsalva performance. Such inconsistency weakens reproducibility and undermines the comparability of findings across operators, institutions, and time points. It also limits the ability of PFUS to support multicenter studies and evidence-based standard clinical pathways. Therefore, the need for standardization in PFUS is not simply procedural; it is fundamental to the scientific and clinical credibility of the modality.

International efforts to address these problems have led to the development of standardized PFUS frameworks, particularly through guidance associated with the International Continence Society (ICS) and the International Urogynecological Association (IUGA). These frameworks emphasize structured examination protocols that include standardized imaging planes, clearly defined anatomical landmarks, dynamic multi-compartment assessment, and consistent performance of functional maneuvers such as rest, contraction, and Valsalva (Pugliesi et al., 2025; Zhu et al., 2024; Li et al., 2025). The goal of such protocols is to improve diagnostic accuracy, reduce measurement variability, and enhance comparability across centers. Standardization also supports more complete reporting by guiding operators toward a systematic sequence of examination and documentation. In theory, this should strengthen inter-operator reliability and facilitate better educational training for novice examiners. However, written guidelines do not automatically translate into uniform practice. The existence of a protocol is not the same as the successful execution of a protocol at the point of care. This distinction matters because the weakness in many ultrasound workflows is not the absence of recommendations, but the inconsistency of their real-time application during the scan.

The practical implementation of standardized PFUS protocols remains limited by several real-world barriers. Studies have pointed to heterogeneity in ultrasound equipment, disparities in operator training, institutional resource differences, and variations in patient characteristics as major obstacles to uniform protocol adherence (Wei et al., 2024; Moro et al., 2025; Pessoa et al., 2024; Zhu et al., 2024). In many settings, sonographers must adapt to different hardware interfaces, variable image quality, and diverse clinical conditions, all of which can disrupt a theoretically standardized workflow. Patient-related factors such as body habitus, bladder filling, involuntary movement, and inconsistency in straining effort further complicate strict adherence to examination protocols (Wei et al., 2024; Pugliesi et al., 2025; Li et al., 2025). These constraints create a gap between guideline-based ideals and the realities of daily practice. In addition, systematic reviews of AI and PFUS research have noted limited external validation and high risk of bias in many published studies, suggesting that even proposed standardized workflows have not yet achieved broad generalizability in routine care (Moro et al., 2025; Pessoa et al., 2024). This means that the problem is not solved by protocol publication alone. What is still missing is an operational mechanism that helps examiners maintain protocol fidelity during the examination itself, especially in settings with variable levels of expertise.

Against this background, artificial intelligence (AI) has begun to attract attention not only as a diagnostic technology but also as a workflow-support tool in medical imaging. This is an important distinction, because much of the public discourse on AI in radiology is still overly fixated on automated diagnosis, while the more immediate and realistic value of AI may lie in supporting acquisition, standardization,

and process consistency. In ultrasound, this shift is particularly relevant because the modality is highly interactive and operator dependent. Recent literature in obstetric and gynecologic ultrasound shows that AI can support automated plane identification, anatomical landmark localization, image quality assurance, and measurement workflows, thereby reducing cognitive burden and improving consistency across operators (Li et al., 2025; Jost et al., 2023). In PFUS specifically, AI-driven methods have been shown to automate segmentation, labeling, and quantitative measurement processes embedded in dynamic imaging workflows (García-Mejido et al., 2025; Botoncea et al., 2025; Qu & Zhang, 2023). This means that AI should not be framed narrowly as a replacement for expert interpretation. Rather, the stronger and more defensible position is that AI functions as an assistive infrastructure that helps clinicians acquire better, more standardized data before interpretation even begins. In operator-dependent examinations such as PFUS, this workflow-oriented role may be more immediately impactful than stand-alone diagnostic prediction.

Evidence supporting this workflow-oriented use of AI is steadily expanding. Garcia-Mejido et al. (2025), for example, demonstrated an automated AI-based workflow for dynamic PFUS capable of segmenting pelvic organs in real-time video frames and deriving clinically relevant measurements. This kind of system shows that AI can function inside the procedural chain of examination rather than merely at the endpoint of diagnosis. Similarly, broader ultrasound literature has shown that AI-guided tools can assist with standard plane acquisition, standardized data capture, and measurement reproducibility, which are all critical to reducing operator-related variation (Li et al., 2025; Jost et al., 2023). Reviews of AI in pelvic floor imaging have also highlighted that automated landmark detection and measurement pipelines may improve consistency among operators with different levels of experience (Botoncea et al., 2025; Qu & Zhang, 2023; García-Mejido et al., 2025). This is particularly relevant in educational and early-career clinical contexts, where the cognitive burden of remembering every step in a complex examination protocol can impair both efficiency and completeness. AI-guided workflow systems may thus operate as cognitive aids that scaffold the examination process in real time. Even so, the literature is careful not to overstate current capabilities. Many authors emphasize that AI in PFUS should currently be understood as workflow augmentation rather than autonomous diagnostic authority, especially given the continuing limitations in explainability, external validation, and multicenter testing (Botoncea et al., 2025; Moro et al., 2025; Pessoa et al., 2024).

One practical embodiment of this workflow-augmentation perspective is the concept of a Protocol Assistant. A Protocol Assistant is not simply a passive digital checklist, but a structured system that guides the operator through predefined procedural steps, from probe placement and sequence selection to image acquisition and documentation. The logic behind this concept is straightforward: if PFUS quality depends heavily on the consistency of examination steps, then a system that assists stepwise adherence may reduce omissions and variability. Existing literature in ultrasound and AI suggests that protocol-guided and navigation-based systems can improve examination completeness, support procedural consistency, and reduce dependence on operator memory, particularly in technically demanding domains (Li et al., 2025; Jost et al., 2023). However, most prior work has focused on general ultrasound, fetal imaging, or highly specific applications such as automated view detection, rather than on comprehensive procedural guidance in PFUS. This matters because PFUS involves unique dynamic and multicompartment challenges, including the need to assess pelvic structures across different functional states and to interpret complex three-dimensional relationships (Vicari et al., 2025; Pugliesi et al., 2025; Zhu et al., 2024). Therefore, borrowing generic AI models from other ultrasound domains without tailoring them to PFUS would be methodologically weak. The field requires a dedicated approach that aligns AI-supported workflow guidance with the specific demands of pelvic floor imaging. Without that specificity, claims of innovation risk being superficial rather than clinically meaningful.

Despite promising progress, several major research gaps remain in the application of AI to PFUS workflows. First, many PFUS AI studies rely on single-center datasets and lack external validation across different populations, operators, and ultrasound platforms, which limits generalizability and readiness for real-world deployment (Botoncea et al., 2025; Moro et al., 2025; Pessoa et al., 2024; García-Mejido et al., 2025). Second, explainability remains underdeveloped, even though clinician trust and clinical integration depend heavily on understanding how AI systems generate recommendations or identify landmarks (Botoncea et al., 2025; Moro et al., 2025). Third, much of the literature remains focused on segmentation, measurement, and classification performance rather than on workflow outcomes such as protocol adherence, examination time, educational value, and implementation feasibility in clinical routines (García-Mejido et al., 2025; Botoncea et al., 2025). Fourth, integrated multicompartment and multimodal approaches for dynamic PFUS are still at an early stage, especially across subgroups with different prolapse stages, parity profiles, or obesity status (Vicari et al., 2025; Pugliesi et al., 2025; Zhu et al., 2024). Fifth, standardized data curation, annotation protocols, and benchmarking frameworks for PFUS-specific AI remain insufficiently developed, which hinders reproducibility and cross-study comparison (Li et al., 2025; Taş et al., 2022). Sixth, regulatory, ethical, and deployment-related issues remain underexplored despite being essential for clinical

translation (Li et al., 2025; Morytko, 2025). Taken together, these gaps show that the field still lacks a rigorously designed, workflow-centered, and practically validated AI support system specifically for pelvic floor ultrasonography.

Based on these considerations, the present study aims to develop and evaluate an Artificial Intelligence-based Protocol Assistant for pelvic floor ultrasonography. The proposed system is designed to support operators throughout the examination process by providing structured guidance aligned with standardized PFUS protocols. This approach directly addresses the persistent problem of inconsistent protocol adherence, incomplete documentation, and inefficiency in operator-dependent ultrasound workflows. Rather than positioning AI as a diagnostic replacement, this study deliberately situates AI as a procedural support mechanism intended to enhance workflow quality and standardization. The development process follows a modified 4D Research and Development framework, focusing on the stages of Define, Design, and Develop to ensure systematic product creation. System feasibility is assessed through expert validation using Aiken's V coefficient, while initial functional testing is conducted to compare protocol adherence and examination time before and after implementation. The novelty of this study lies in integrating AI-based workflow assistance with standardized PFUS procedural requirements in a structured development framework. By doing so, this study seeks to contribute not only a technical tool but also a practical model for bridging the gap between protocol recommendations and real-time examination practice in pelvic floor ultrasonography.

METHODOLOGY

This study employed a Research and Development (R&D) approach to develop and preliminarily evaluate an Artificial Intelligence-based Protocol Assistant for pelvic floor ultrasonography. The R&D approach was selected because the development of a clinical workflow-support system requires a systematic and iterative process integrating problem identification, design, prototyping, refinement, and evaluation to ensure alignment between technical functions and clinical needs (Swift, 2021; Mungovan et al., 2021; Mazur-Biały et al., 2020). The development process followed a modified 4D model consisting of Define, Design, Develop, and Disseminate, although the present study was limited to the Develop stage. The Define stage focused on identifying problems related to operator variability and inconsistent adherence to standardized pelvic floor ultrasound protocols through literature review and field observation. The Design stage involved formulating the system architecture, workflow logic, and evaluation instruments, while the Develop stage included prototype implementation, expert validation, system refinement, and initial functional testing. The system was designed as an AI-based workflow support tool that translated standardized pelvic floor ultrasound protocols into stepwise procedural guidance, including probe positioning, imaging plane orientation, technical parameter adjustment, sequence control, and structured documentation. This design is consistent with previous literature emphasizing the importance of standardized, dynamic, and clinically validated development frameworks for imaging workflows and AI-assisted clinical systems (Botoncea et al., 2025; Qu & Zhang, 2023; Shek & Dietz, 2025; Hakim et al., 2023).

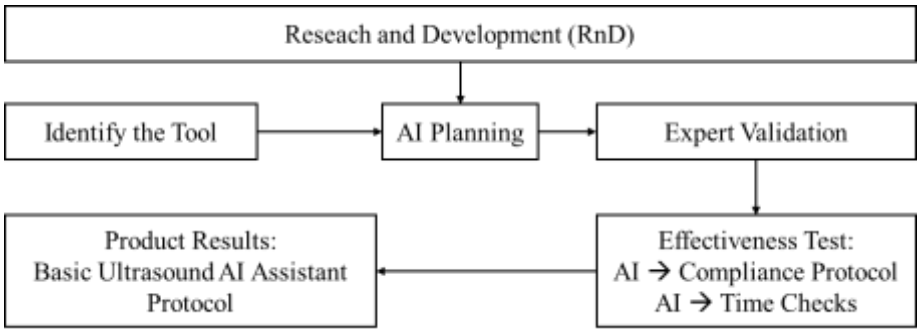

Figure 1. Conceptual framework

Initial system functionality was evaluated using a one-group pretest-posttest design with a within-subject comparison, in which each participant performed pelvic floor ultrasound examinations under two conditions: without and with the Protocol Assistant system. This design was considered appropriate for early-stage system evaluation because it allows direct assessment of feasibility, usability, and functional performance change before more rigorous controlled testing is undertaken (Giarenis et al., 2020; Youssef et al., 2021; Notenboom-Nas et al., 2022). A within-subject approach was used to minimize inter-operator variability and enable direct comparison of workflow performance under both conditions in the same individual (Wei et al., 2024; Bellussi & Dietz, 2021). The study involved two groups of subjects selected purposively: expert validators and sonographers participating in initial functional testing. Expert validation was conducted by at least three experts in ultrasonography and radiologic technology, while the functional test involved 50 sonographers with basic ultrasound competency. Data were collected sequentially by

first recording examinations performed without system assistance and then with the Protocol Assistant. The instruments included an expert validation questionnaire using a 4-point Likert scale, a 29-item protocol adherence checklist derived from standardized pelvic floor ultrasound procedures, and examination time measurement from scan initiation to completion of documentation. The use of adherence checklists and examination time as workflow indicators is supported by prior studies showing that these measures capture both procedural reliability and efficiency in structured clinical workflows (Pereira et al., 2021; Bilgiç & Beji, 2020; Giarenis et al., 2020).

Expert validation data were analyzed using Aiken's V coefficient to determine the content validity of the system components, as this method is widely recommended for quantifying expert agreement on item relevance and feasibility in system and instrument development (Cramer et al., 2023; Sullivan et al., 2025; Braga et al., 2023; Atılgan & Altuntaş, 2020; Bø et al., 2022). Protocol adherence and examination time were first analyzed descriptively to compare workflow performance across conditions. Inferential analysis was then conducted using the Wilcoxon Signed-Rank Test following normality assessment with the Shapiro-Wilk test, since the data were paired and did not satisfy parametric assumptions. The use of Wilcoxon is methodologically appropriate for early-stage workflow studies involving paired observations, modest sample sizes, and non-normally distributed data (Wei et al., 2024; Notenboom-Nas et al., 2022; Bilgiç & Beji, 2020). Statistical significance was determined at $\alpha = 0.05$. The results were interpreted as evidence of initial feasibility and functionality of the developed system, rather than proof of clinical effectiveness or diagnostic superiority. This limitation is important because one-group pretest-posttest designs remain vulnerable to testing and contextual effects, and therefore subsequent controlled studies are needed to confirm causal impact more robustly (Giarenis et al., 2020; Youssef et al., 2021; Qu & Zhang, 2023).

RESULT

The development of the Artificial Intelligence-based Protocol Assistant for pelvic floor ultrasonography was successfully completed using a Research and Development approach with a modified 4D model up to the Develop stage. The resulting system was specifically designed as a workflow-support tool that translates standardized pelvic floor ultrasound protocols into a structured and sequential examination process. Conceptually, this design is consistent with previous literature showing that structured workflows, protocol templates, and embedded checklists improve procedural consistency, reduce omissions, and enhance reproducibility in medical imaging practice (Botoncea et al., 2025; Hamour et al., 2021; Roth et al., 2024). The prototype integrated three principal components, namely procedural guidance, workflow control, and structured documentation. Procedural guidance provided step-by-step instructions from initial probe positioning to final image and data recording, while workflow control applied a sequence-lock mechanism to prevent progression before completion of prior steps. Structured documentation ensured that each completed examination component was recorded systematically, thereby improving data consistency and traceability. From a workflow perspective, such integration is important because standardized and interoperable imaging processes are considered essential not only for examination quality but also for broader scalability and future AI deployment in clinical ecosystems (East et al., 2025; Roth et al., 2024; Yan et al., 2024).

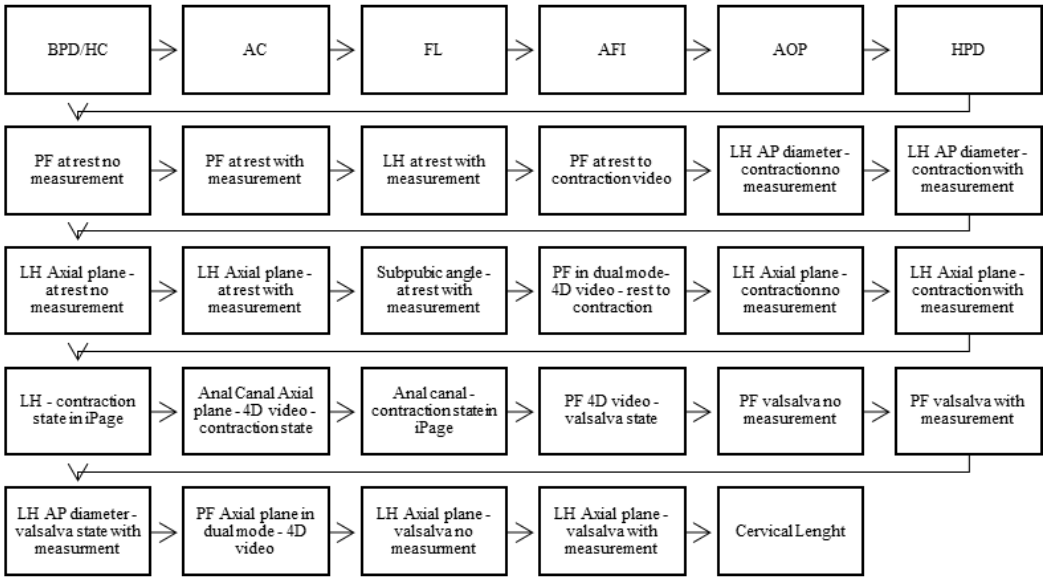

Figure 2. Workflow Protocol Assistant Sistem Artificial Intelligence

Based on the workflow diagram and interface presented in the study, the Protocol Assistant organized the examination into a comprehensive sequence that included biometric measurements, pelvic floor assessments under rest, contraction, and Valsalva conditions, and additional parameters such as Angle of Progression, Head Perineum Distance, and cervical length. This structured sequence ensured that each imaging component was acquired and documented before the user proceeded to the next step. The user interface also supported guided navigation through clearly organized menus, progress indicators, and completion markers, allowing operators to monitor their advancement throughout the examination. These features are methodologically relevant because the literature consistently indicates that real-world workflow integration is a key determinant of whether standardized systems are actually adopted and able to improve performance in daily practice (East et al., 2025; Korfiatis et al., 2025; Roth et al., 2024). In other words, a protocol may be theoretically sound yet operationally ineffective if it is not embedded in a usable and intuitive interface. The present system appears to address that problem by converting abstract protocol requirements into an actionable navigation framework. This is also aligned with previous findings that structured digital workflow systems are most effective when they guide sequencing, support operator awareness, and reduce the cognitive burden associated with remembering complex procedural steps (Hamour et al., 2021; Chen et al., 2023; Roth et al., 2024).

Tabel 1. Aiken's V Results on the Technical Feasibility of Artificial Intelligence Systems

No	Statement	Aiken's V	Category
1	Easy-to-use interface display	0,98	Valid
2	AI provide appropriate and relevant feedback	0,98	Valid
3	The system navigation is clear and not confusing	0,98	Valid
4	The system correctly detects the inspection steps	0,98	Valid
5	Stable system during use	0,98	Valid
Average		0,98	Valid

The results of the expert validation indicate that all evaluated aspects of the system achieved an Aiken's V value of 0.98, which falls within the "very valid" category. This consistently high score across all items suggests a strong level of agreement among experts regarding the relevance, clarity, and appropriateness of the system's design and functionality. Specifically, the interface display was considered easy to use, indicating that the system supports user-friendly interaction. The provision of appropriate and relevant feedback reflects the system's capability to guide users effectively during the examination process. In addition, the clarity of system navigation suggests that users can operate the system without confusion, which is essential for maintaining workflow efficiency. The system's ability to correctly detect inspection steps further demonstrates its functional accuracy in guiding procedural sequences. Moreover, the system was assessed as stable during use, indicating reliability in operational performance. The average Aiken's V value of 0.98 reinforces the conclusion that the developed system possesses very high content validity. Overall, these findings provide strong preliminary evidence that the AI-based Protocol Assistant is feasible and appropriate for implementation as a workflow-support tool in pelvic floor ultrasonography.

Table 2. Validation Results of Protocol Assistant Artificial Intelligence System Experts

Assessment Aspects	Average Aiken's V Value	Category
Protocol content compatibility	≥ 0,98	Reliable
System functions	≥ 0,98	Reliable
Interface display	≥ 0,98	Reliable
Average	**≥ 0,98**	Reliable

The expert validation results demonstrate that all assessed aspects of the Artificial Intelligence-based Protocol Assistant system achieved an Average Aiken's V value of ≥ 0.98, which is categorized as "reliable." This indicates a very high level of agreement among experts regarding the appropriateness and quality of the system across multiple dimensions. Specifically, the protocol content compatibility being rated as reliable suggests that the system successfully aligns with established pelvic floor ultrasonography standards and accurately represents the required examination procedures. The system functions aspect also achieved a high validity score, indicating that the operational features of the system such as workflow control, step detection, and guidance mechanisms are considered appropriate and effective for clinical use. Meanwhile, the interface display being categorized as reliable reflects that the system is designed with adequate usability, clarity, and accessibility, supporting smooth interaction for users. The consistently high Aiken's V values across all components, with an overall average of ≥ 0.98, provide strong evidence that the system

meets expert expectations in terms of content accuracy, functional performance, and interface design. These findings suggest that the developed Protocol Assistant has a high level of feasibility and is suitable for implementation as a workflow-support tool in pelvic floor ultrasonography, particularly in enhancing standardization and reducing operator variability.

These findings are methodologically defensible because Aiken's V is widely recognized as an appropriate statistic for establishing content validity in the early development phase of instruments, protocols, and system components prior to broader empirical testing (Cramer et al., 2023; Sullivan et al., 2025; Braga et al., 2023; Atılgan & Altuntaş, 2020; Bø et al., 2022). In the context of pelvic floor ultrasonography, where standardized landmarks, planes, and procedural steps depend heavily on expert consensus, high Aiken's V values provide meaningful preliminary evidence that the system reflects accepted professional expectations (Botoncea et al., 2025; Qu & Zhang, 2023; Shek & Dietz, 2025). The experts specifically rated the system highly in terms of instructional clarity, completeness of anatomical coverage, appropriateness of technical parameter recommendations, and usability of the interface. Qualitative feedback primarily focused on improving readability and refining the clarity of instructions, and these suggestions were incorporated before functional testing. Even so, high expert validity should not be overstated as final proof of clinical readiness, because methodological literature clearly notes that content validity must eventually be complemented by empirical reliability assessment and external validation across settings and devices (Wei et al., 2024; Cramer et al., 2023; Botoncea et al., 2025).

Table 3. Comparison of Loss Protocol Assistant Levels Before and After Artificial Intelligence Systems

No.	Protokol	*Loss* Before AI			*Loss* After AI	
		Quantity	%	Loss Description	Quantity	%
1	BPD/HC	7	14,0%	Not acquired / incomplete	0	0,0%
2	AC	7	14,0%	Not acquired / incomplete	0	0,0%
3	FL	10	20,0%	Not acquired / incomplete	0	0,0%
4	AFI	10	20,0%	Not acquired / incomplete	0	0,0%
5	AOP	7	14,0%	Angle was not measured	0	0,0%
6	HPD	8	16,0%	Distance not measured	0	0,0%
7	PF at rest no measurement	10	20,0%	View not acquired	0	0,0%
8	PF at rest with measurement	10	20,0%	Measurement missing	0	0,0%
9	LH at rest with measurement	14	28,0%	Measurement missing	0	0,0%
10	PF at rest to contraction video	6	12,0%	Video not saved	0	0,0%
11	LH AP diameter - contraction no measurement	7	14,0%	View not acquired	0	0,0%
12	LH AP diameter - contraction with measurement	8	16,0%	Measurement missing	0	0,0%
13	LH Axial plane - at rest no measurement	9	18,0%	View not acquired	0	0,0%
14	LH Axial plane - at rest with measurement	7	14,0%	Measurement missing	0	0,0%
15	Subpubic angle - at rest with measurement	5	10,0%	Measurement missing	0	0,0%
16	PF in dual mode- 4D video - rest to contraction	5	10,0%	Video not saved	0	0,0%
17	LH Axial plane - contraction no measurement	7	14,0%	View not acquired	0	0,0%
18	LH Axial plane - contraction with measurement	11	22,0%	Measurement missing	0	0,0%
19	LH - contraction state in iPage	7	14,0%	iPage not performed	0	0,0%
20	Anal Canal Axial plane - 4D video - contraction state	9	18,0%	Video not saved	0	0,0%
21	Anal canal - contraction state in iPage	12	24,0%	iPage not performed	0	0,0%
22	PF 4D video - valsalva state	8	16,0%	Video not saved	0	0,0%

No.	Protokol	*Loss* Before AI			*Loss* After AI	
		Quantity	%	Loss Description	Quantity	%
23	PF valsalva no measurement	7	14,0%	View not acquired	0	0,0%
24	PF valsalva with measurement	10	20,0%	Measurement missing	0	0,0%
25	LH AP diameter - valsalva state with measurment	13	26,0%	Measurement missing	0	0,0%
26	PF Axial plane in dual mode - 4D video	5	10,0%	Video not saved	0	0,0%
27	LH Axial plane - valsalva no measurment	8	16,0%	Measurement missing	0	0,0%
28	LH Axial plane - valsalva with measurement	8	16,0%	Measurement missing	0	0,0%
29	Cervical Lenght	7	14,0%	Cervical length not measured	0	0,0%
	Rata-Rata	**8,3**	**16,7%**		**0,0**	**0,0%**

The analysis of protocol adherence demonstrated one of the strongest findings of the study. Using a 29-step checklist, the study found that average protocol loss decreased from 16.7% in examinations performed without the Protocol Assistant to 0.0% after system implementation. Before implementation, protocol omissions occurred across several important stages, including biometric measurements, pelvic floor imaging under dynamic maneuvers, video acquisition, measurement recording, and structured documentation. The most frequent omissions were observed in levator hiatus measurement at rest and anterior-posterior diameter measurement during Valsalva, suggesting that the greatest weaknesses occurred in technically detailed and dynamically demanding components of the examination. After implementation, all protocol losses were eliminated across the full checklist, indicating complete adherence when the structured workflow system was used. This result is strongly supported by previous literature showing that structured protocols, checklists, and embedded reporting templates substantially improve adherence, reduce omissions, and enhance consistency in imaging workflows (Hamour et al., 2021; Chen et al., 2023; Roth et al., 2024). From a methodological standpoint, the finding also reinforces the argument that protocol adherence is an appropriate and meaningful indicator of workflow performance because it captures whether the intended process is executed completely and systematically. The Wilcoxon Signed-Rank Test further confirmed that this improvement was statistically significant, with all 50 participants demonstrating higher adherence scores during system-assisted examinations, which suggests that the effect was consistent rather than isolated.

Tabel 4. Wilcoxon Signed Rank Test

Variable Comparison	Z	Asymp. Sig. (2-tailed)
Kepatuhan_Protokol_Dengan_AI – Kepatuhan_Protokol_Tanpa_AI	-6.173	0.000

The examination time analysis also showed that the Protocol Assistant contributed to improved workflow efficiency. Descriptively, examination duration decreased after system implementation, indicating that structured guidance and workflow control helped operators complete the procedure more efficiently. This pattern is consistent with prior imaging and ultrasound literature showing that AI-assisted and protocol-based systems can shorten workflow duration by reducing trial-and-error behavior, minimizing redundant actions, and accelerating repetitive tasks such as measurement sequencing and documentation (Yan et al., 2024; Shi, 2025; Korfiatis et al., 2025). In this study, normality testing using the Shapiro-Wilk test indicated that the data were not normally distributed, justifying the use of a non-parametric approach. The Wilcoxon Signed-Rank Test demonstrated a statistically significant reduction in examination time, with all 50 participants showing shorter durations when using the system. This suggests that the Protocol Assistant not only improved completeness of protocol execution but also supported more efficient procedural flow. That combination matters, because efficiency gains without procedural accuracy are meaningless, while improved adherence accompanied by excessive time burden may weaken practical adoption. The present findings indicate that both dimensions moved in a favorable direction simultaneously, which strengthens the functional value of the system.

Taken together, these findings indicate that the Artificial Intelligence-based Protocol Assistant has strong preliminary feasibility as a structured workflow-support system for pelvic floor ultrasonography. The system demonstrated high expert-rated content validity, eliminated protocol loss, and

significantly reduced examination time, suggesting that it can improve both procedural reliability and workflow efficiency. These findings are consistent with the broader literature arguing that structured workflows and AI-assisted guidance systems are most valuable when they function as tools for reducing operator variability, omission errors, and inefficient task sequencing rather than as stand-alone diagnostic replacements (Botoncea et al., 2025; García-Mejido et al., 2025; Qu & Zhang, 2023). However, the interpretation of these results must remain disciplined. This study provides evidence of initial functionality and feasibility**,** not definitive proof of clinical effectiveness, diagnostic superiority, or generalizability across institutions. Prior literature is clear that early success in prototype evaluation must be followed by reliability studies, external validation, and deployment-focused research before a system can be considered ready for broader clinical implementation (Wei et al., 2024; Korfiatis et al., 2025; East et al., 2025; Botoncea et al., 2025). That is the real next step, and anything less would be methodologically weak.

DISCUSSION

System Development and Workflow-Based Approach

The development of the Artificial Intelligence-based Protocol Assistant in this study was grounded in a central practical problem in pelvic floor ultrasonography, namely the high degree of operator dependency that affects examination consistency, completeness, and reliability. In pelvic floor imaging, differences in operator experience can influence probe positioning, landmark recognition, maneuver execution, image acquisition, and documentation quality, which in turn may reduce the comparability of findings across examinations. The system developed in this study addressed this issue by embedding standardized pelvic floor ultrasound protocols into a structured workflow that guided operators through sequential examination steps. This approach is consistent with the broader literature describing workflow-based AI systems as cognitive aids that standardize data capture, reduce dependence on individual expertise, and support more reproducible imaging processes rather than replacing clinical judgment (Botoncea et al., 2025; Qu & Zhang, 2023; García-Mejido et al., 2025; Hamour et al., 2021; Yan et al., 2024). The translation of standardized clinical protocols into algorithmic pathways, including the identification of anatomical landmarks and assessment under rest, contraction, and Valsalva conditions, reflects an implementation of AI as workflow augmentation rather than diagnostic automation. This distinction is important because the real value of AI in this context lies not in making autonomous conclusions, but in ensuring that clinically relevant inputs are acquired in a complete, orderly, and standardized manner. In other words, the system functions as a scaffold for procedural consistency. That is a stronger and more defensible contribution than claiming diagnostic intelligence the study did not test.

Feasibility of the System and the Role of Enforced Workflow

The expert validation results indicated that the developed system had very high content validity, with Aiken's V values of 0.98 or higher across protocol suitability, functionality, and interface design. These findings suggest that the system was considered highly relevant, clear, and feasible by domain experts, which is an important early indicator of system appropriateness before broader implementation. However, the more substantive strength of the system lies in how its design operationalized workflow enforcement. The sequence-lock mechanism ensured that users could not move to the next stage before completing the current step, thereby reducing the opportunity for skipped procedures and incomplete documentation. This design aligns with literature from other high-stakes healthcare domains showing that enforced workflows, standardized checks, and structured sequence verification can substantially reduce human error and maintain procedural integrity (Xia et al., 2020; Ford et al., 2020; Ramezani et al., 2025; Mechalakos et al., 2021). The relevance of this mechanism to pelvic floor ultrasonography is obvious: omission errors in dynamic measurements or documentation do not merely reduce administrative completeness; they directly compromise interpretive reliability. The system therefore should be understood not simply as an interface innovation, but as a procedural control architecture. Even so, high expert validity does not by itself prove real-world effectiveness, generalizability, or sustained usability. The literature consistently warns that content validity must be complemented by empirical reliability testing, external validation, and deployment-focused assessment before a system can be considered clinically mature (Botoncea et al., 2025; Wei et al., 2024; Olakotan & Yusof, 2021).

Protocol Adherence, Diagnostic Consistency, and Cognitive Support

One of the most important findings of this study was the complete elimination of protocol loss after implementation of the Protocol Assistant, with the average protocol loss declining from 16.7% to 0.0% and the difference reaching statistical significance. This result strongly supports the argument that structured workflow systems can improve protocol adherence by minimizing omission errors and reducing dependence on unaided memory. The effect was especially pronounced in technically demanding steps, such as levator hiatus measurements and dynamic Valsalva-related assessments, which are precisely the components most vulnerable to variation when operators rely on experience alone. The literature supports this interpretation by showing that standardized templates, explicit sequencing, and structured workflow support improve documentation

completeness, reduce omissions, and enhance consistency of imaging practice across operators and settings (Hamour et al., 2021; Roth et al., 2024; Yan et al., 2024; Olakotan & Yusof, 2021). In pelvic floor ultrasonography specifically, improved adherence to standardized landmarks, imaging planes, and functional maneuvers contributes directly to diagnostic consistency because interpretation becomes based on more comparable inputs (Alshiek et al., 2023; Qu & Zhang, 2023; Curtain & Gugelmin-Almeida, 2024). The present findings therefore do not only show improved compliance; they also imply a more stable diagnostic foundation. At the same time, the improvement should not be romanticized. Because the system enforced completion, the observed gains may reflect successful procedural control more than a genuine increase in independent operator competence. That is not a weakness of the system, but it is a limitation in how the outcome should be interpreted.

Workflow Efficiency and Reduction of Cognitive Load

In addition to improving adherence, the system significantly reduced examination time, indicating that structured AI-assisted workflow support can improve operational efficiency without increasing procedural burden. This finding is consistent with prior studies showing that AI-based imaging systems can accelerate workflows by automating or structuring routine tasks such as measurement sequencing, landmark localization, frame analysis, and documentation, thereby reducing manual repetition and shortening examination or reporting time (Li et al., 2025; García-Mejido et al., 2025; Botoncea et al., 2025; Yan et al., 2024). In the present study, the reduction in examination time is plausibly explained by three overlapping mechanisms: reduced trial-and-error during acquisition, faster procedural recall due to structured guidance, and lower cognitive burden because the system externalized task sequencing and progress monitoring. This interpretation aligns with the literature describing AI systems as tools that redistribute cognitive work by handling routine, repetitive, and error-prone components of clinical workflow, allowing operators to focus more on execution and interpretation (Botoncea et al., 2025; Qu & Zhang, 2023; Vicari et al., 2025). However, efficiency gains in AI-enabled systems are never automatic. Reviews consistently emphasize that time savings depend on interface quality, integration with institutional infrastructure, interoperability with PACS or EHR, and acceptance by clinicians; otherwise, the system may introduce additional overhead rather than reduce workload (Roth et al., 2024; East et al., 2025; Korfiatis et al., 2025; Shi, 2025). In this case, the consistent reduction across all participants suggests that the system's structure supported real efficiency gains, although some portion of the effect may also reflect familiarity from the fixed sequence of testing conditions. That possibility should be acknowledged rather than ignored.

LIMITATIONS AND FUTURE DIRECTIONS

Several limitations should shape the interpretation of these findings. First, the one-group pretest-posttest design without a control group limits causal inference, because improvements may partly reflect learning effects, task familiarity, or Hawthorne effects rather than the intervention alone. Second, the evaluation focused on process-level outcomes, namely protocol adherence and examination time, without assessing downstream outcomes such as image quality, diagnostic accuracy, inter-operator reproducibility, or patient-level benefit. That means the study demonstrates workflow feasibility, not clinical effectiveness. Third, the study was conducted in a single setting with a limited implementation context, which restricts generalizability across institutions, patient populations, and ultrasound platforms. These concerns mirror broader limitations identified in the AI and PFUS literature, particularly the persistent lack of external validation, limited cross-device testing, and uncertainty regarding generalizability beyond controlled development settings (Botoncea et al., 2025; Qu & Zhang, 2023; Hamour et al., 2021; Olakotan & Yusof, 2021). Fourth, the study did not examine user acceptance, long-term usability, trust, explainability, or alert fatigue, all of which are known to influence whether AI systems are actually adopted in clinical routines. Finally, issues related to governance, integration with PACS and EHR, data provenance, privacy, and regulatory readiness were not addressed, even though the literature identifies them as essential prerequisites for sustainable clinical deployment (Wellnhofer, 2022; Heilemann et al., 2023; Bernard, 2025). Future research therefore should move beyond proof-of-concept and examine multicenter validation, randomized or crossover designs, reliability outcomes, implementation science variables, and clinically meaningful endpoints. Without that progression, the system remains promising but not yet proven.

Overall, this study provides preliminary evidence that an Artificial Intelligence-based Protocol Assistant can function effectively as a workflow-support system in pelvic floor ultrasonography. Its main contribution lies in demonstrating that AI can be used to standardize examination processes, reduce omission errors, and improve efficiency while preserving the operator's role in clinical decision-making. That positioning matters, because the literature increasingly supports AI in imaging not as a replacement for clinicians, but as a cognitive and procedural aid that stabilizes workflows and improves the quality of acquired inputs (García-Mejido et al., 2025; Botoncea et al., 2025; Qu & Zhang, 2023). The present findings fit that model well. Still, the real test is not whether the prototype works in a preliminary study, but whether it remains useful, trusted, interoperable, and clinically relevant across diverse real-world settings. That is the standard the next phase of research must meet.

CONCLUSION

This study demonstrates that the development of an Artificial Intelligence-based Protocol Assistant for pelvic floor ultrasonography is feasible and functionally effective as a workflow-support system. The system, developed using a Research and Development approach with a modified 4D model, successfully translates standardized pelvic floor ultrasound protocols into a structured and sequential examination process. Expert validation results indicate very high content validity, while functional testing shows that the system significantly improves protocol adherence by eliminating omission errors and reduces examination time across all participants. These findings confirm that AI can be effectively positioned as a cognitive and procedural support tool that enhances workflow standardization, reduces operator dependency, and improves efficiency without replacing clinical decision-making. However, the findings should be interpreted cautiously, as the study is limited to initial feasibility and process-level outcomes, without assessing diagnostic accuracy, reproducibility, or patient-related impacts.

Future research should focus on strengthening the evidence base through more rigorous designs, such as randomized controlled or crossover studies, to better isolate the effect of the system. Further evaluation should also include clinical outcome measures, such as image quality, diagnostic reliability, and inter-operator consistency, as well as user-centered factors such as usability, acceptance, and cognitive workload. In addition, multicenter validation involving diverse operators, patient populations, and ultrasound systems is necessary to ensure generalizability and scalability. From an implementation perspective, integration with hospital information systems, attention to data governance and privacy, and improvement of system explainability are essential for real-world adoption. Beyond clinical use, the system also holds potential as a training tool to support skill standardization among novice operators, although this role requires dedicated evaluation.

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