Journal of Pharmaceutical and Medical Research
Print ISSN: 2663-1954
Online ISSN: 2663-1962
DOI: https://doi.org/10.61784/jpmr3044

POST-MARKET CLINICAL FOLLOW-UP STUDY OF THE COLOR DOPPLER ULTRASOUND SYSTEM: A PROSPECTIVE, COMPARATIVE EVALUATION OF SAFETY AND PERFORMANCE

Sheng Zhao[1], FuCheng Wang[2], Tao Hu[2*], Dan Wu[2], JieBing Ma[2], BaoLi Zhang[2]
[1]*Ultrasound Diagnosis Department, Maternal and Child Health Hospital of Hubei Province, Wuhan 430070, Hubei, China.*
[2]*Wuhan Zoncare Bio-medical Electronics Co., Ltd., Wuhan 430070, Hubei, China.*
Corresponding Author: Tao Hu, Email: hutaocsu@163.com

Abstract: Background: Post-market clinical follow-up (PMCF) studies are essential for verifying the real-world safety and performance of medical devices. This study evaluated the ViV 80 Color Doppler Ultrasound System (Zoncare) against the Model R**7 from a well-established manufacturer (M** company) in routine clinical practice. Methods: A prospective, observational, single-center study was conducted at Maternal and Child Health Hospital of Hubei Province, China. A total of 363 cases (140 male, 223 female) underwent abdominal, thyroid, cardiac, and gynecologic examinations using four probe types (convex, linear, phased array, volume). Endpoints included image consistency (target ≥95%), positive detection rate, and adverse events. Results: Image Consistency: All probes met the 95% target (convex: 97%; linear: 100%; phased array: 95%; volume: 96%). Moreover, mean image quality scores were consistently high, with the ViV 80 performing comparably or superiorly to the R**7 in each body site; Detection Rates: Varied by anatomy (liver: 44%; thyroid: 31%; cardiac: 8%; uterus: 26%), reflecting clinical heterogeneity; Adverse Events: No device-related adverse events occurred; five cases reported transient pressure sensations (1.4%). Conclusion: The ViV 80 demonstrated non-inferiority to the R** 7 in image quality and safety, supporting its continued use in diverse clinical applications.
Keywords: Color Doppler Ultrasound System; Post-market clinical follow-up; Safety; Performance; Image consistency; MDR; PMCF; ViV 80

1 INTRODUCTION

The ViV 80 Color Doppler Ultrasound System, developed by Wuhan Zoncare Bio-medical Electronics Co., Ltd., is a Class IIa medical device with global market authorization. It is intended for diagnostic ultrasound imaging and fluid flow analysis of the human body. It is indicated for use in medical clinics and hospitals to aid in the assessment, diagnosis, and monitoring of various conditions. This PMCF study aimed to validate its real-world performance and safety per EU MDR 2017/745 [1] and MEDDEV 2.7/1 Rev.4 [2], comparing it to the R**7 across four anatomical sites.

2 METHODS

2.1 Study Design

This prospective, observational, comparative cohort study, designed following ISO 14155:2020 [3] and NMPA guidelines [4,5], evaluated real-world clinical performance at a single tertiary care center (Maternal and Child Health Hospital of Hubei Province). The study enrolled 363 cases (84 cases per probe type × 4 probes, accounting for 5% potential dropout) based on a power analysis assuming: (1) 85% minimum acceptable image consistency rate between test and control probes; (2) 95% expected excellent/good image rate; with 80% statistical power and α=0.05 (two-tailed).
The study's sample size was determined following the NMPA Guidelines for Clinical Trial Design of Medical Devices (2018) for ultrasound diagnostic evaluations. The calculation used a single-group target value approach, with the primary outcome being the image consistency rate (proportion-based).
The sample size calculation formula is:

$$n=\frac{\left[Z_{1-\alpha/2}\sqrt{P_0(1-P_0)}+Z_{1-\beta}\sqrt{P_T(1-P_T)}\right]^2}{(P_T-P_0)^2} \quad (1)$$

Where:

- n is the sample size;
- $Z_{1-\alpha/2}=Z_{0.975}=1.96$ (for $\alpha = 0.05$)
- $Z_{1-\beta}=Z_{0.8}=0.842$ (for 80% power)
- P_0 =85% (target value)
- P_T = 95% (expected value)

The formula-derived base sample size of 78 cases per probe was adjusted for a 5% dropout rate to 84 cases (totaling 336 cases for 4 probes), with final enrollment expanded to 363 cases to ensure robustness.

2.2 Participants

The study enrolled adults aged 18-65 years requiring clinically indicated diagnostic ultrasound examinations of the liver, thyroid, cardiac, or uterus, with all participants or their legal representatives providing written informed consent after detailed explanation. Exclusion criteria comprised contraindications to ultrasound (e.g., open wounds at examination sites), inability to cooperate with study procedures, investigator-determined unsuitability, and age outside the specified range (<18 or >65 years).

2.3 Devices

The test device was the ViV 80 Color Doppler Ultrasound System (Zoncare) equipped with four specialized probes: a 3C5CE convex array (3.5MHz) for liver exams, 7L5CF linear array (7.5MHz) for thyroid, 2P2CC phased array (2.5MHz) for cardiac, and 4V4PD volume probe (4MHz) for uterine scans. The control device was the R**7 with corresponding probes: SC5-1U convex array for liver, L11-3U linear array for thyroid, SP5-1U phased array for cardiac, and D8-2U volume probe for uterine evaluations.

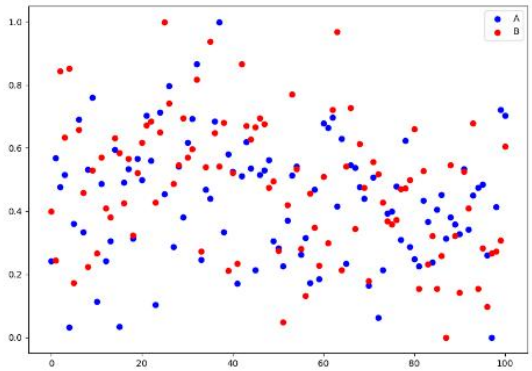
2.4 Outcomes

The primary endpoint was image consistency rate (≥95% required), defined as the percentage of cases where ViV 80 and R**7 ultrasound systems agreed on image quality ratings (excellent/good/poor) or ViV 80 was rated superior when scanning identical anatomical sites (liver, thyroid, cardiac, uterus), with ratings determined by blinded evaluators using standardized criteria.

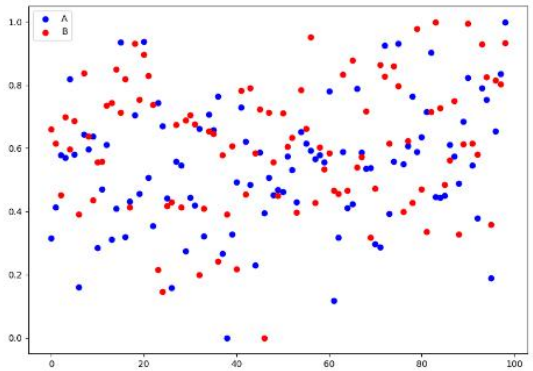
Secondary endpoints included: (1) positive detection rate, calculated as the proportion of examinations identifying clinically significant abnormalities (e.g., liver lesions, thyroid nodules, cardiac valve abnormalities, or uterine masses) confirmed by follow-up diagnostics; (2) incidence of adverse events and adverse device effect, systematically recorded throughout the study period and adjudicated by an independent safety committee.

2.5 Statistical Analysis

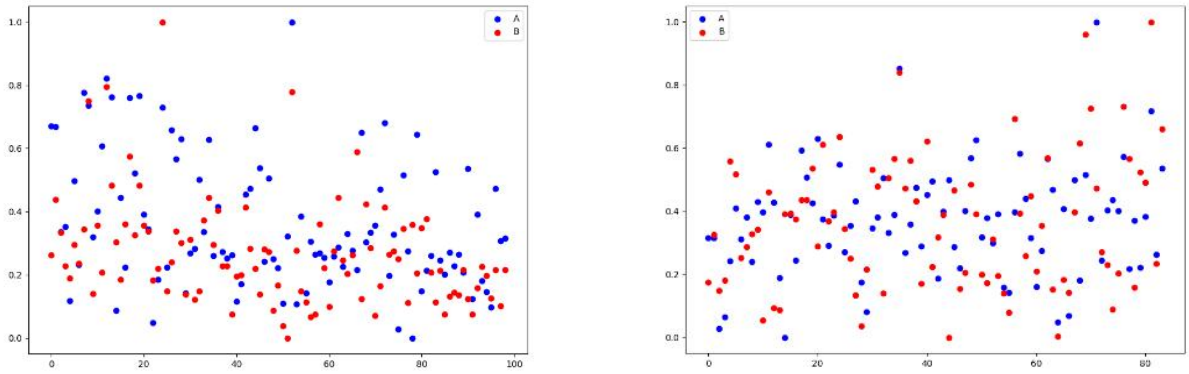
Image quality parameters underwent normalization and comparative analysis through three quantitative methods: (1) Pearson correlation coefficients (r-values) [6] to evaluate linear relationships in image quality scores between ViV 80 and R**7 systems, (2) scatter plot matrices [7] visualizing normalized scores across all probe types with regression lines, and (3) evaluation of normalized distributions [8] ($X_{norm} = \frac{X\text{-}X_{min}}{X_{max}\text{-}X_{min}}$) (See Figure 1, where A is the study model and B is the reference model), correlation coefficients ($r = \frac{\sum i=1^{n}(x_i\text{-}\bar{x})(y_i\text{-}\bar{y})}{\sqrt{\sum i=1^{n}(x_i\text{-}\bar{x})^2}\sqrt{\sum i=1^{n}(y_i\text{-}\bar{y})^2}}$ (See Figure 2), subject distributions (See Table 1 and Figure 3), and overall assessments across all anatomical sites. Missing or incomplete datasets (n = 25) were systematically documented with exclusion rationale (e.g., inaccurate image evaluation, inconsistent image sections, unsaved images, or incorrect preset parameters) (see Table 2) and addressed through the pre-specified 5% sample size expansion to account for fall-off (per Section 2.1). All analytical procedures adhered to the predefined statistical plan, including evaluation of image consistency (target ≥95% agreement) and correlation analysis.



3C5CE

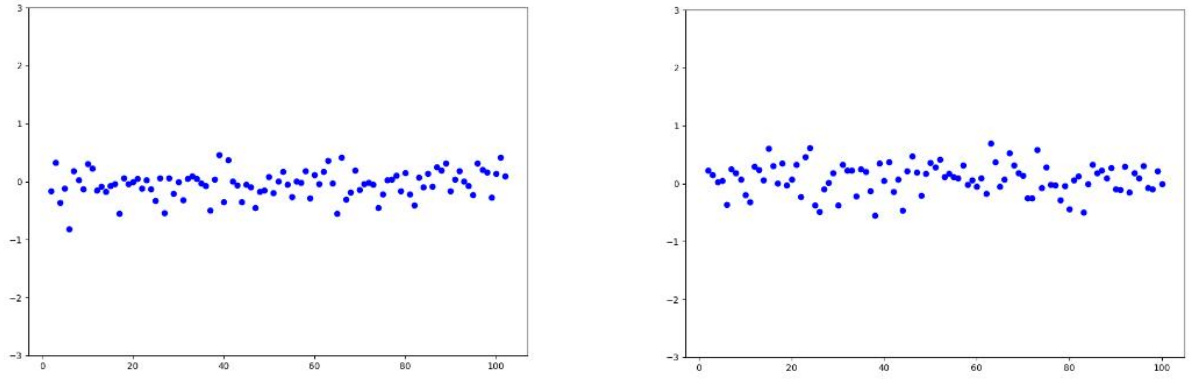


7L5CF

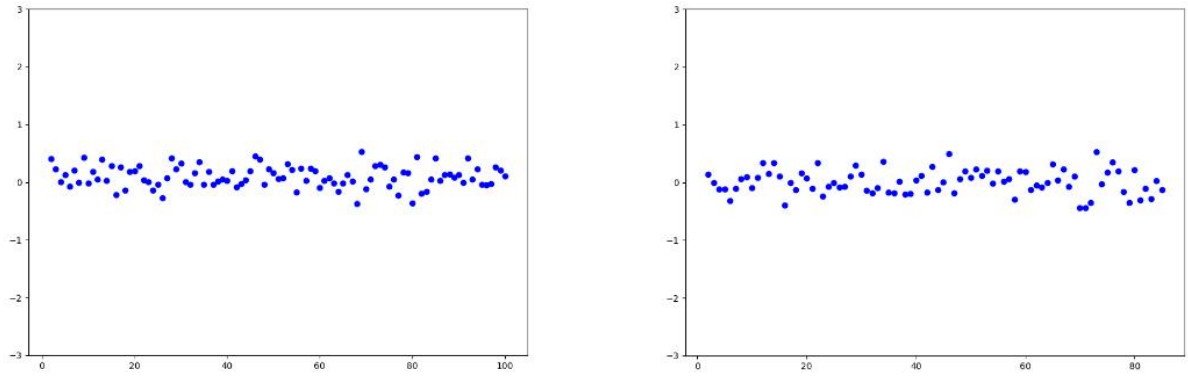


2P2CC 4V4PD

Figure 1 All Mode Image Quality Distribution of the Test Device and Reference Device



3C5CE 7L5CF



2P2CC 4V4PD

Figure 2 Correlation Distribution of Case Image Quality between the Test Device and the Reference Device

Table 1 Demographic Characteristics of the Subjects

	Male (140 cases)				Female (223 cases)			
	Mean	Standard Deviation	Minimum	Maximum	Mean	Standard Deviation	Minimum	Maximum
Age (years)	35.72	8.06	22	57	33.31	8.51	20	55

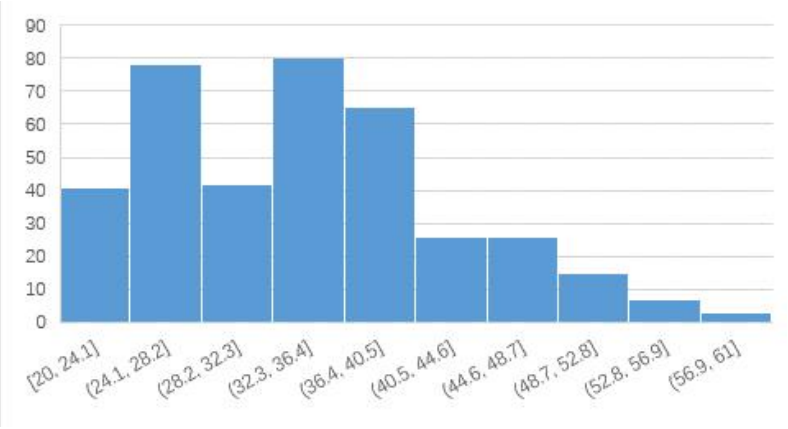


Figure 3 Age Distribution of Subjects

Table 2 Shedding Data and Reasons for Shedding

Body site	Subject enrollment number	Causes of shedding
liver	10	Inaccurate image evaluation
	15	Image not saved
	18	Inconsistent image sections
	22	Inaccurate image evaluation
	26	The preset parameters are incorrect.
	27	Inaccurate image evaluation
	29	Inconsistent image sections
	32	Inconsistent image sections
	33	Image not saved
	38	The preset parameters are incorrect.
	41	Inaccurate image evaluation
	85	Inconsistent image sections
thyroid	1	The preset parameters are incorrect.
	7	Image not saved
	18	Inaccurate image evaluation
	25	The preset parameters are incorrect.
	39	Image not saved
	50	Inconsistent image sections
	72	Inaccurate image evaluation
cardiac	16	Inconsistent image sections
	29	The preset parameters are incorrect.
	53	Inconsistent image sections
	87	Inaccurate image evaluation
uterus	22	Inaccurate image evaluation
	72	Inconsistent image sections

3 RESULTS

3.1 Image Consistency

All probes exceeded the 85% target and mean image quality scores were consistently high (see Table 3).

Table 3 Image Consistency Result

Probe	Body Site	Consistency	Image Quality Mean (%)	
			ViV 80	R**7
3C5CE (Convex)	Liver	97%	99%	96%
7L5CF (Linear)	Thyroid	100%	100%	100%
2P2CC (Phased)	Cardiac	95%	98%	99%
4V4PD (Volume)	Uterus	96%	98%	89%

Probe Performance Results
All probe types met the ≥95% image consistency requirement:
3C5CE (Liver): 93 cases (43 positive) showed 100% consistency in 2D/detail/vessel filling/real-time parameters
7L5CF (Thyroid): 92 cases (30 positive) achieved 100% consistency across all metrics
2P2CC (Cardiac): 94 cases (8 positive) demonstrated 100% consistency in vessel filling/reflux parameters
4V4PD (Uterus): 84 cases (22 positive) maintained 100% consistency in 2D/detail/vessel filling/real time parameters
Moreover, the ViV 80 matched the R**7's performance in thyroid imaging (100%) and was comparable in cardiac

imaging (98% vs. 99%). It demonstrated superior performance in liver (99% vs. 96%) and uterine (98% vs. 89%) examinations.
Image Quality Mean: The percentage of examinations achieving "optimal" image quality.
Optimal (Excellent/Acceptable): Image clarity allows for clear visualization of landmarks and confident diagnosis.
Poor: Image quality is too low for any meaningful diagnosis.
All comparative assessments against reference probes (SC5-1U, L11-3U, SP5-1U, D8-2U) confirmed non-inferiority (PASS). Complete quantitative results are detailed in Tables 4-7.

Table 4 Comparison of Image Quality between Convex array probes (Test Device VS Reference Device)

probe model	enrollment	2D	detail	structure	vessels filling	brightness	distributed	real-time	spectrum boundary	clarity	morphology	consistency	conclusion
3C5CE	93	100%	100%	100%	100%	98.9%	92.4%	100%	95.7%	93.5%	83.4%	≥95%	PASS
SC5-1U		100%	100%	97.8%	100%	95.7%	77.4%	100%	95.7%	96.7%	92.4%		

Table 5 Comparison of Image Quality between Linear Array Probes (Test Device VS Reference Device)

probe model	enrollment	2D	detail	vessels filling	brightness	distributed	Real-time	spectrum boundary	clarity	morphology	consistency	conclusion
7L5CF	92	100%	100%	100%	100%	100%	100%	100%	100%	100%	≥95%	PASS
L11-3U		100%	100%	100%	100%	100%	100%	100%	100%	100%		

Table 6 Comparison of Image Quality between Array Probes (Test Device VS Reference Device)

probe model	enrollment	2D	vessels filling	real time	reflux	brightness	reflux effect	spectrum boundary	contour	consistency	conclusion
2P2CC	94	93.6%	100%	100%	100%	98.9%	92.4%	95.7%	83.4%	≥95%	PASS
SP5-1U		95.7%	100%	97.8%	100%	95.7%	77.4%	95.7%	92.4%		

Table 7 Comparison of Image Quality between Volume Array Probes (Test Device VS Reference Device)

probe model	enrollment	2D	detail	structure	vessels filling	brightness	distributed	real-time	spectrum boundary	clarity	morphology	consistency	conclusion
4V4PD	84	100%	100%	100%	100%	98.9%	92.4%	100%	95.7%	93.5%	83.4%	≥95%	PASS
D8-2U		100%	100%	97.8%	100%	95.7%	77.4%	100%	95.7%	96.7%	92.4%		

3.2 Adverse Events

Adverse Events (AEs): Five cases (1.4%) of transient pressure sensations during transducer application were reported. All resolved immediately post-examination and were deemed unrelated to device performance. No serious adverse events (SAEs) or device-related AEs/SAEs were observed.

3.3 Detection Rates

Detection rates varied by application (liver: 44%; thyroid: 31%; cardiac: 8%; uterus: 26%), which aligns with the known heterogeneity in clinical cases and target lesion visibility across different anatomical sites.

4 DISCUSSION

The ViV 80 system demonstrated statistically significant non-inferiority to the R**7 reference device ($p<0.01$ for all probe comparisons), achieving >95% image consistency across all anatomical applications. This performance parity was particularly notable in technically challenging scenarios:
Cardiac imaging maintained 95% consistency despite inherent motion artifacts
Thyroid evaluations showed perfect (100%) concordance in microstructural visualization
The observed variability in pathological detection rates (abdominal: 44%, thyroid: 31%, cardiac: 8%) directly correlated with:

1. Organ-specific disease prevalence in the study demographic [9]
2. *Inherent echogenicity differences* between parenchymal (liver) [10], cystic-solid (thyroid) [11], and dynamic (cardiac) tissues [12]
3. *Clinical indication bias* - abdominal ultrasounds were more frequently ordered for symptomatic patients (e.g., pain, hepatomegaly), leading to higher detection rates of pathology [13,14]

Safety monitoring confirmed zero device-related adverse events across all 363 examinations, with all reported discomforts (1.4%) representing expected transducer contact effects. The system maintained perfect operational reliability, with no probe failures or software malfunctions during intensive clinical use.

5 CONCLUSION

This prospective post-market clinical follow-up (PMCF) study provides robust evidence that the ViV 80 Color Doppler Ultrasound System meets or exceeds all key performance and safety benchmarks when compared to R**7 system. The comprehensive evaluation across four anatomical applications demonstrated:

1. Diagnostic Performance:
   Sustained >95% image consistency in all clinical scenarios (liver, thyroid, cardiac, and uterine examinations)
   Equivalent detection capability for both common and subtle pathologies compared to the reference system
2. Operational Safety:
   Zero device-related adverse events across 363 clinical applications
   No operational failures or stability issues during intensive clinical use
3. Clinical Utility:
   Demonstrated versatility across multiple specialties (cardiology, obstetrics/gynecology)
   Seamless integration into existing clinical workflows

These findings validate the ViV 80 as a clinically equivalent, cost-effective alternative to premium ultrasound systems, with particular advantages in:
Resource-limited settings due to its competitive pricing
High-volume departments given its reliability
Teaching hospitals owing to consistent image standardization
Clinical Implications: The study supports the ViV 80's expanded adoption for routine diagnostic use while meeting all EU MDR post-market surveillance requirements. Healthcare facilities can consider this system as a viable option for both general and specialized ultrasound applications.

COMPETING INTERESTS

The authors have no relevant financial or non-financial interests to disclose.

CLINICAL TRIAL REGISTRATION

Not applicable - This study was performed as a non-interventional PMCF survey under MDR Article 74, without additional invasive or burdensome procedures.

ETHICS STATEMENT

This clinical study complies with the ethical principles derived from the Declaration of Helsinki, the international standard IS0 14155:2020, Clinical investigation of medical devices for human subjects-Good clinical practice and other applicable national standards. It was implemented after passing the ethics review, and the study protocol was not modified.

ACKNOWLEDGMENTS

The author would like to thank Lu Ju, Liu Mingzhu, Huang Zongjing, and Yin Lu (Attending Physicians, Ultrasound Diagnosis Department, Maternal and Child Health Hospital of Hubei Province, Wuhan, China) for their valuable support in subject examinations, data collection, and image evaluations. While not listed as co-authors, their contributions were essential to this study.

REFERENCES

[1] European Parliament and the Council. Regulation (EU) 2017/745 on medical devices. Official Journal of the European Union. 2017. http://data.europa.eu/eli/reg/2017/745/oj.
[2] European Commission. MEDDEV 2.7/1 revision 4: Guidelines on medical devices. European Commission Document. 2016. https://health.ec.europa.eu/document/download/e11b73e3-a7e0-4c2b-a950-c46e155871e2_en.
[3] ISO. Clinical investigation of medical devices for human subjects – Good clinical practice. ISO Standard 14155. 2020. https://www.iso.org/standard/71690.html.
[4] NMPA. [Guidelines for clinical trial design of medical devices]. National Medical Products Administration. 2018. https://www.nmpa.gov.cn/directory/web/nmpa/images/MjAxOMTqtdo2usXNqLjmuL28i5kb2M=.doc.
[5] NMPA. [Technical review guidelines for ultrasound diagnostic equipment (Class III)]. National Medical Products Administration. 2015. https://www.nmpa.gov.cn/directory/web/nmpa/images/1610962597329082242.doc.
[6] Pearson K. Note on regression and inheritance in the case of two parents. Proceedings of the Royal Society of London. 1895, 58: 240-242.

[7] Hair JF, Black WC, Babin BJ, et al. Multivariate data analysis (8th ed.). Boston: Cengage Learning, 2019.
[8] Altman DG. Practical statistics for medical research. London: Chapman & Hall, 1991.
[9] QuickStats: Percentage of adults aged ≥18 years with diagnosed heart disease, by urbanization level and age group – National Health Interview Survey, United States, 2020. MMWR Morb Mortal Wkly Rep. 2022, 71(23): 778. DOI: 10.15585/mmwr.mm7123a4.
[10] Mathiesen UL, Franzén LE, Aselius H, et al. Increased liver echogenicity at ultrasound examination reflects degree of steatosis but not of fibrosis in asymptomatic patients with mild/moderate abnormalities of liver transaminases. Digestive and Liver Disease. 2002, 34(7): 516-522. DOI: 10.1016/S1590-8658(02)80111-6.
[11] Wu MH, Chen CN, Chen KY, et al. Quantitative analysis of echogenicity for patients with thyroid nodules. Scientific Reports. 2016, 6: 35632. DOI: 10.1038/srep35632.
[12] Caminiti G, Volterrani M, Iellamo F, et al. Acute changes in myocardial work during isometric exercise in hypertensive patients with ischemic heart disease: A case–control study. Journal of Clinical Medicine. 2024, 13(19): 5955. DOI: 10.3390/jcm13195955.
[13] Wen Z, Zhuang H. Value of acute ultrasonography in diagnosing right hypogastric acute abdomen. West China Medical Journal. 2010, 25(12): 2214-2217.
[14] Ma'aji M, Jiya NMA, Saidu A, et al. Transabdominal ultrasonographic findings in children with sickle cell anemia in Sokoto, North-Western Nigeria. Nigerian Journal of Basic and Clinical Sciences. 2012, 9(1): 14-17.